

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

The Medicare Beneficiary Complaint Process

A Rusty Safety Valve



**AUGUST 2001
OEI-01-00-00060**

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EXECUTIVE SUMMARY

PURPOSE

To reevaluate the effectiveness of the beneficiary complaint process of the Medicare Peer Review Organization program.

BACKGROUND

Complaints as a Means to Oversee Quality of Care

Complaints can serve as a means of identifying practitioners and providers who pose harm and, if necessary, triggering interventions and follow-up. Since 1987, the Medicare beneficiary complaint process has been a statutory responsibility of Medicare Peer Review Organizations (PROs).

Previous Office of Inspector General Report

In 1995, the Office of Inspector General issued a report on the PROs' beneficiary complaint process that identified three flaws: (1) Federal confidentiality regulations precluded the PROs from responding to complainants in a meaningful way, (2) PROs received too few complaints to identify patterns of poor care, and (3) the complaint process was lengthy. The Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration) responded positively to our report. It worked on revising the confidentiality regulations, but reports that it has been unable to publish a final rule.

This Inquiry

This inquiry reexamines the PROs' complaint process. It is based on a mail survey to PROs, aggregate data on PRO complaints, site visits to 3 PROs, a review of 82 complaints at those 3 PROs, PRO budget data, and stakeholder discussions, among others.

THE SIGNIFICANCE OF THE PROs' COMPLAINT PROCESS

Two main reasons underscore why the complaint process is an important safety valve:

Identifying Instances of Poor Care. On average, the PROs identified quality problems in 13 percent of medical record reviews initiated by complaints between August 1997 and July 1999. They identified such serious concerns as inappropriate transfer, delay in treatment, and missed medications, among others.

Limits to Other Complaint Processes. Professional licensing boards have historically struggled with quality-of-care complaints. The Joint Commission on Accreditation of

Healthcare Organizations gives complaints limited attention during its surveys. The medical malpractice system tends to have long delays and financial costs that work against Medicare beneficiaries in malpractice litigation.

FINDINGS

The PROs' Complaint Process is an Ineffective Safety Valve for Medicare Beneficiaries. It Has Improved Little Over the Past 5 Years.

Its accessibility is questionable. We called 10 PROs and repeatedly reached busy signals at 2, reached recordings at 2, and were referred to a licensure board by another. PROs report that beneficiaries often lack a clear understanding of the complaint process.

It rarely triggers any intervention beyond a letter for substantiated complaints. PROs called for a corrective action in 6 of 66 complaints with confirmed concerns that we reviewed. They involved clarifying policies or conducting in-service training.

It fails to provide a meaningful response to complainants. Current procedures requiring physician consent before PROs can share their review results with complainants continue to preclude the PROs from responding substantively to complainants.

PROs Face Two Major Obstacles to Achieving a More Effective Beneficiary Complaint Process.

CMS' contracts with PROs treat complaints as a distinctly minor activity. The contracts stress quality improvement and payment error reduction.

The PROs tend to be more oriented toward the medical community than to the beneficiary community. This helps them in conducting quality improvement projects but can hinder them in developing a more effective beneficiary complaint process.

RECOMMENDATION

CMS should provide Medicare beneficiaries with an effective complaint process that meets the eight criteria identified in our template.

In our draft report, we presented a series of recommendations on how CMS could achieve an effective complaint process. In this final report, we have revised our recommendations and present CMS with two options on how it can achieve this.

Option 1: CMS could fix the complaint process within the existing PRO program.

Toward that end, CMS must make the beneficiary complaint process a prominent part of the PRO program, specify its expectations of an effective process through its contracts, consider different contracting approaches, and hold the PROs more accountable for providing an effective complaint process.

Option 2: CMS could establish a complaint process outside of the PRO program.

This option represents a significant departure from how CMS has handled beneficiary complaints to date and would require legislative change. CMS could establish an entirely new program or contract mechanism focused on complaints and beneficiary outreach. It could develop new mechanisms, such as mediation, for dealing with certain types of complaints. Or it could build on existing entities that already conduct similar work, such as State survey and certification agencies, State medical licensure boards, and the State Health Insurance Partnership Program.

Issues for CMS to Consider

The two options above have advantages and disadvantages for CMS to weigh as it considers how to best achieve effective complaint process for beneficiaries. Below we highlight those issues we consider as paramount.

- To what extent would establishing a complaint process outside of the PROs isolate the PROs from beneficiaries, who are the centerpiece of CMS' programs?
- To what extent would fixing the complaint process within the PRO program exacerbate the tension between the quality improvement and complaint responsibilities of the PROs?
- To what extent does each option require legislative and regulatory changes to ensure that the complaint process functions with the appropriate authority and scope?
- What are the resource implications of each option?

COMMENTS

CMS did not provide detailed comments on the recommendations in our draft report. We look forward to receiving such comments in response to this final report. We solicited and did receive comments from the American Health Quality Association, Citizen Advocacy Center, AARP (formerly the American Association of Retired Persons), and the American College of Physicians-American Society of Internal Medicine. All commenters agreed that an effective complaint process is important for Medicare beneficiaries and that the PRO program's focus on quality improvement is an appropriate one that can co-exist with a more effective complaint process. Some offered further recommendations, such as an informal complaint resolution process or options for contract changes. We urge CMS to consider these comments.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	
INTRODUCTION	1
SIGNIFICANCE OF THE PROs' COMPLAINT PROCESS	4
FINDINGS	
Complaint Process is an Ineffective Safety Valve	6
Obstacles to a More Effective Complaint Process	14
RECOMMENDATION	16
COMMENTS on the DRAFT REPORT	21
APPENDICES	
A: Profile of Complaints Reviewed	23
B: Comments on the Draft Report	26
C: Endnotes	49

INTRODUCTION

PURPOSE

To reevaluate the effectiveness of the beneficiary complaint process of the Medicare Peer Review Organization program.

BACKGROUND

The Complaint Process as a Means to Oversee Quality of Care

The Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration) relies on a variety of quality oversight mechanisms to ensure that high quality health care and services are delivered to Medicare beneficiaries. One of these mechanisms is the complaint process, contractually administered by the Medicare Peer Review Organizations (PROs). The PROs' complaint process provides Medicare beneficiaries and their families a forum to have their complaints taken seriously and investigated appropriately. It also complements other oversight efforts, ranging from surveying hospitals to collecting data on performance measures.

Providing a complaint process specifically for Medicare beneficiaries has been a responsibility of the PROs since 1987, when Congress enacted the Omnibus Budget Reconciliation Act of 1986.¹ That law mandates that PROs conduct "an appropriate review of all written complaints about the quality of services" paid for by Medicare, inform the beneficiary or representative of the final disposition of the complaint, and provide the practitioner and/or provider concerned with reasonable notice and opportunity for discussion.²

Previous Office of Inspector General Report

In 1995, the Office of Inspector General (OIG) issued a report on the PROs' beneficiary complaint process.³ In that report we found the PROs' complaint process to be flawed in three significant ways: (1) Federal confidentiality regulations precluded the PROs from responding to complainants in a meaningful, substantive way, (2) PROs received too few complaints to identify patterns of poor care, and (3) the process of investigating and responding to complaints was lengthy. Furthermore, we found that Medicare beneficiaries were often unaware of their opportunities to complain to PROs about the quality of their medical care.

Based on those findings, we recommended that CMS give the highest priority to requiring PROs to respond in a substantive manner to the complainant. We also called for CMS to enhance Medicare beneficiaries' awareness of PROs and the complaint process, and to streamline that process.

CMS responded positively to our report. It assigned a taskforce (part of the Medicare Technical Advisory Group) the responsibility to improve the complaint process in light of the flaws we identified. That task force included representatives from CMS, the PROs, the American Medical Association, AARP (formerly the American Association of Retired Persons), the American Hospital Association, and the Citizen Advocacy Center, among others. The task met regularly in the period following the 1995 OIG report.

As a result of recommendations made by the task force, CMS changed its guidelines for how long the complaint process should take, dropping the total days allowed from 250 to 165 days and developing model letters to improve the readability of PRO responses to complainants.⁴ It also conducted three pilot programs to explore new approaches to different aspects of the complaint process (mediation to resolve complaints, structured implicit review to assess medical records, and various changes in investigating and managing complaints).⁵ However, it has yet to respond to the findings and recommendations from the pilot evaluation.

CMS also began the process of revising the confidentiality regulations, but faced considerable hurdles in issuing a rule to allow a substantive response to complainants without explicit physician consent. CMS reports that it has been unable to publish the rule. It was on hold for over a year and withdrawn as of February 13, 2001, according to CMS' Unified Agenda, the semiannual regulatory agenda published May 14, 2001.⁶

This Inquiry and Report

Having released our previous report 5 years ago, we now take a second look at the PROs' beneficiary complaint process. This inquiry and report focus on the effectiveness of the complaint process and its role as a quality oversight mechanism. We exclude any examination of other major aspects of the PROs' work, such as quality improvement projects and the payment error reduction program.

Our inquiry drew on several data sources. We received national budget data for the fifth and sixth contract periods from CMS.⁷ We collected information from CMS' data contractor on the volume and outcome of beneficiary complaint reviews as well as the type of and audience for PRO outreach efforts from August 1997 through July 1999. We also conducted a mail survey of the PROs in each State plus the District of Columbia, for which we achieved a 100 percent response rate.⁸ In addition to completing the survey, we asked each PRO to provide us with 3 examples of recent responses to beneficiary complaints; we received 101 such responses.⁹ We visited 3 PROs of different sizes in States representing 15 percent of the beneficiary population. While on site, we interviewed staff involved in complaints and reviewed 82 completed beneficiary complaint files, 16 of which involved no confirmed quality-of-care problems and 66 of which involved at least 1 confirmed quality-of-care problem. We also interviewed stakeholders in CMS, the American Health Quality Association (of which PROs are members), AARP, and the Citizen Advocacy Center (which represents public members of PRO boards, among others). Finally, we reviewed relevant laws and documents, such as the PRO manual and the pilot evaluation, *The Medicare Beneficiary Complaint Alternative Methods Study*, among others.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

THE SIGNIFICANCE OF THE PROs' COMPLAINT PROCESS

In 1995, CMS set forth its vision of the successful PRO in 5 years. CMS envisioned that the PROs will “have earned a position of trust in the eyes of plans, providers, and practitioners and beneficiaries . . .based on responsive investigation of complaints and protection of consumers.”¹⁰

Five years have passed since CMS wrote this vision statement. The PROs' complaint process, mandated by statute, continues to serve as the key instrument for protecting the 38 million Medicare beneficiaries from practitioners and providers who pose harm. The complaint process can act as a means of identifying such practitioners and providers and, if necessary, triggering appropriate interventions and follow-up. This corresponds with one of the three purposes of the PRO program that CMS defined in its recent contract with the PROs: to protect Medicare beneficiaries.¹¹

Below we identify two main reasons that underscore why the complaint process is an important safety valve in quality oversight.

Identifying Instances of Poor Care

Complaints can expose serious instances of substandard care. In the 2-year period from August 1997 through July 1999, PROs completed 9,099 medical record reviews in response to complaints. On average, PROs identified problems in 13 percent of those reviews. Our previous inquiry reported similar proportions of confirmed reviews: across all PROs, between 10 and 15 percent of reviews initiated by complaints led to at least 1 confirmed problem.¹² Notably, according to the more recent data, 3 PROs confirmed problems in as many as 29 percent of records reviewed.

From our complaint file review, we found several examples of patient risk and harm that PROs identified and confirmed as problems through the complaint process. These examples represent technical quality concerns, which deal with clinical decisions and expertise:

- C **Inappropriate transfer.** During bladder surgery in an ambulatory surgical center, a beneficiary suffered complications that were improperly treated. The surgical center transferred him by wheelchair to a hospital six blocks away. A PRO physician reviewer called this transfer method “repulsive” and “negligent” because the ailing beneficiary was wheeled down the street dressed in a hospital gown with his family following him.
- C **Delay in treatment.** A beneficiary experienced a sharp decline in health due to a delay of treatment for an abdominal aortic aneurism.

- C **Missed medications.** For 6 days after being transferred from a hospital to a skilled nursing facility, a beneficiary failed to receive his medications as ordered by his physician to treat his heart failure and lung problems, despite continued complaints to the nursing home staff from his wife.

Each of the examples above concerned the technical quality of care. But we also found complaints that alleged problems with the quality of services, such as facility maintenance, communication, and staff attitudes. One PRO official characterized these service concerns in terms of beneficiaries' perception of and overall satisfaction with their health care experience. For example, a beneficiary's daughter complained that her mother was confused about caring for her eye after cataract surgery because her physician failed to clearly communicate follow-up instructions. Another beneficiary complained that staff in his skilled nursing facility placed him in a wheelchair that was insufficiently cleaned of urine. Service quality concerns that are ongoing, particularly in long-term care, can affect residents' and patients' quality of life.

See appendix A for more details on the complaints we reviewed.

Limits to Other Complaint Processes

Several entities other than PROs address quality-of-care complaints from Medicare beneficiaries as well as from the general population. But each entity has some limits. Hospitals and most other health facilities have their own internal complaint mechanisms, but are limited to those specific facilities. State survey agencies that certify facilities for Medicare consider complaints a priority, but focus on those that relate specifically to the Medicare conditions of participation and can only address provider concerns. The Joint Commission on Accreditation of Healthcare Organizations, which accredits most hospitals that participate in Medicare, gives complaints limited attention during its surveys and rarely schedules special surveys in response to complaints.¹³ Ombudsmen programs serve as advocates for residents in long-term care facilities and often investigate complaints, but generally lack clinical expertise to review medical records. Professional licensing boards, such as those that license physicians, routinely respond to complaints, but have historically struggled with quality-of-care complaints.¹⁴

Medicare beneficiaries can also choose to pursue complaints through the courts. Malpractice court cases can address quality concerns, but memory lapses, pretrial delays, and limited finances tend to work against the elderly and ill in malpractice litigation, which is often lengthy and expensive. Moreover, malpractice attorneys working on a contingency fee basis have less incentive to accept retired or elderly clients such as Medicare beneficiaries who may receive minimal monetary awards from lost work earnings.¹⁵

FINDINGS

The PROs' complaint process is an ineffective safety valve for Medicare beneficiaries. It has improved little over the past 5 years.

We developed a template for an effective complaint process based on prior inspection work on dialysis facility oversight.¹⁶ In testimony before Congress on dialysis facilities, CMS endorsed the elements as essential to an effective complaint system.¹⁷ We think it is just as relevant to the complaint process of Medicare PROs. The table below profiles the elements in our template and how well PROs fared in each element.

Element	Characteristics of an Effective Complaint Process	Characteristics of the PRO Complaint Process
1. Accessibility	Complainants are aware of the system and find it easy to use.	Hotline calls are inconsistently answered. Success of PRO outreach is unknown.
2. Investigative capacity	Appropriate experts, resources, and methods are available to assess complaints and determine if they are part of an underlying pattern.	PROs rely on medical record review, which is their strength, but they are unlikely to identify patterns. Medical record review is limited to addressing technical quality concerns.
3. Interventions and follow-through	Substantiated complaints result in appropriate corrective action. Monitoring assures compliance.	Most common interventions are letters. Corrective actions are rare. Few referrals to other entities. Little follow-up.
4. Quality improvement orientation	Complaints guide quality improvement efforts.	Quality improvement projects rarely stem from complaints: only one PRO implemented a project based on complaints.
5. Responsiveness	Responses to complainants are regular, substantive, and clear.	Current procedures continue to preclude PROs from responding substantively; physicians often fail to consent to disclosure. PROs vary in their responses; they report that beneficiaries are frustrated.
6. Timeliness	Each step is completed within an established, reasonable time frame, and mechanisms exist to deal with emergent complaints in an expedited manner.	Most complaints exceed the established timeframes for reviewing complaints.
7. Objectivity	The review process is unbiased, balancing the rights of each party.	Information gathered suggests that the process is fair.
8. Public accountability	Complaint information is made available to the public.	Little complaint information is publicly available.

Five years ago we examined the PROs' beneficiary complaint process and found it to be seriously flawed. This time, we examined it more closely, gauging it by each element in our template. What we found was a complaint system that falls short in each element, with the exception of objectivity. Beneficiaries looking for an easy-to-use complaint system that will hold physicians and facilities accountable for quality-of-care problems and respond to beneficiaries in a meaningful way will be left frustrated and disappointed by the PROs' beneficiary complaint process. Below we offer, in more detail, our assessments of the major elements in our template.

Accessibility

An effective complaint process is widely known and easy to use.

Accessibility is questionable. Our experience calling a sample of PROs raised concerns about how easily beneficiaries can access information through the toll-free numbers that PROs maintain. Though PROs train staff to assist beneficiaries in submitting complaints, we had trouble reaching such trained staff (see box).

In addition to calling 10 PROs, we called 1-800-MEDICARE, the phone number for a Medicare information hotline, which is commonly included on Medicare publications. The first day we reached a busy signal. Calling again the next day, we reached a recording that presented no menu option for PROs or for quality-of-care concerns. Although CMS has not measured the accuracy of PRO information provided by telephone, it reported that in 1999 only two of three Medicare beneficiaries received responsive answers from Medicare sources, meaning one of every three received either no answer or an incorrect answer.¹⁸

Calls to 10 PROs

We called PROs in 10 States containing 54 percent of the Medicare population and asked operators to explain how a beneficiary with a quality-of-care complaint can use the PRO complaint process.

- 2 Calls Reached Busy Signals.** *Repeated attempts over several hours resulted in busy signals.*
- 2 Calls Reached Recordings.** *One requested an access code, without explanation. One recorded phone numbers for return calls.*
- 6 Calls Reached Operators.** *One provided us with contact information for the State medical board, and explained that the board is the appropriate place for Medicare beneficiaries to bring quality-of-care complaints. One transferred us to a voice mail system without providing any information. Four provided accurate information.*

According to our PRO survey, even beneficiaries who are aware of the PROs often lack a clear understanding of the complaint process. Many PROs identified inadequate beneficiary understanding of the complaint process as a barrier to achieving effectiveness.¹⁹

All PROs conduct outreach to improve beneficiary awareness and understanding of the complaint process. The most common outreach activities are presentations at venues such

as area agencies on aging and senior centers. Many PROs also coordinate outreach with State Health Insurance Partnership programs, Departments of Public Health, and the Social Security Administration, among others. However, PROs are not required to coordinate their outreach efforts with other relevant State entities. PRO contracts merely require them to take note of and avoid duplicating the outreach efforts of others.²⁰

The effectiveness of these outreach efforts, however, is unknown. For example, States conducting the highest rates of outreach do not necessarily have the highest rates of complaints, as measured by how many medical records they review.²¹ Outreach budgets are limited; under the fifth contract, average outreach spending constituted about 6 to 7 percent of the total PRO budget.²² Despite CMS' target to improve beneficiary education in its FY 2000 Performance Plan, the level of outreach funding did not change significantly under the sixth contract.²³

Investigative Capacity

An effective complaint process has the appropriate experts, resources, and methods available to assess complaints.

Strength in medical record review. PROs review medical records to investigate complaints. They have not only the expertise necessary for reviewing medical records, but also the authority to request the medical records, plus the access to the medical specialists needed for such reviews. PROs have a depth of experience in reviewing medical records that CMS, State survey agencies, and others are hard-pressed to match.

PROs request only those medical records related to the complaints they receive. This often means they review multiple records. In our review of 82 complaints, 20 complaints involved 2 care settings and 5 involved 3 care settings—which meant these PROs reviewed at least 55 records for those 25 complaints.

Unlikely to review a sample of records. PROs tend to treat complaints as individual incidents, rather than as potential signs of systemic problems. When a PRO confirms a quality-of-care concern in a particular record, it is unlikely to pull extra records to determine whether an underlying pattern exists. PROs do have the authority to review extra records under such circumstances, but are unlikely to know whether the medical licensing board, State survey agency, or other overseer is investigating the same physicians or facilities. Without such knowledge or additional reviews, the likelihood of documenting a pattern based only on PRO data is low. One PRO medical director noted that identifying a pattern relies on “corporate memory.” According to the responses to our survey, just 9 of 50 PROs identified a pattern of concerns based on reviewing complaints under their fifth contract, a period exceeding 3 years.

Limits of medical record review. While medical record review is well-suited to investigating complaints about technical quality of care, PROs also receive complaints

concerning service quality. Medical records shed little light on those concerns. We asked officials at 24 PROs how they handled service quality, such as complaints about communication or facility maintenance. Twenty-two indicated they referred those complaints to others.²⁴ They simply consider service-related complaints non-PRO issues. Among the 20 service-related concerns we identified during our on-site review of complaints, we saw documentation that PROs referred 2 to another entity. According to our site visits, PROs rarely hear back any results of investigations on referred complaints.

Finally, PROs do little beyond the medical record review to investigate complaints, and are not expected to do more. They do not routinely conduct interviews with the parties involved, although in many cases, some semblance of a beneficiary interview occurs if a beneficiary complains to the PRO hotline staff, who then translate the complaint into writing.²⁵

Interventions and Follow-Through

An effective complaint process triggers appropriate interventions and monitoring based on substantiated complaints.

Most common interventions are letters. PROs rarely take any action beyond a notification letter to providers and practitioners in response to confirmed quality concerns based on complaints. PROs consider these letters to be educational interventions because they include references to how the care should have been handled by the physician or facility. PROs generally prefer these educational approaches, finding them more in line with the quality improvement orientation that is a centerpiece of their contracts. We reviewed 66 complaints with confirmed concerns. A PRO confirms a concern only after multiple layers of review, including an opportunity for the physician and provider in question to comment or provide additional information. In each of those 66 cases the PRO responded with such a letter.²⁶

Occasionally, PRO interventions exceeded the notification letter. In 6 of the 66 complaints with confirmed concerns, the PROs, based on the severity of the review findings, also called for a corrective action plan. In five of those six, the PRO found the facility responsible for the quality-of-care concern; in one case, the physician. PROs called for corrective action aimed at preventing further problems, including updating or clarifying policies or conducting in-service training. We saw no examples of a PRO calling for remedial training, coursework, or special supervision. Furthermore, we saw little evidence of particular follow-through by the PRO to ensure that the facilities had, in fact, changed their policies. We found no example of a PRO pulling extra records for review to determine if the problem persisted, for example. In each case, the PROs' letters indicated that the problem would be entered into a database and tracked to determine whether a pattern developed—but one medical director told us that little tracking actually occurred.²⁷

Referrals to licensing boards rare. More serious interventions, such as referring a physician to the State medical board based on the findings of a medical record review, were even rarer.²⁸ We surveyed the PROs about such referrals based on beneficiary complaints. Just 9 of the 50 PROs that responded to our survey reported making such a referral at least once during their fifth contract—a period that exceeded 3 years. Likewise, PRO referrals to State survey and certification agencies are uncommon: six PROs reported making such referrals for confirmed concerns during their fifth contracts.²⁹

Patterns difficult to establish. PROs cite the need for establishing a pattern of concerns through medical record review before applying an intervention beyond the traditional notification letter.³⁰ Determining whether a concern is part of a larger pattern is crucial for the PROs to determine an appropriate intervention. However, establishing a pattern is increasingly difficult because they lack the volume of case review to identify a pattern. They do, however, have the authority to investigate whether a larger pattern exists by requesting additional cases to review.³¹ But they rarely invoke it. In responding to our survey, 9 out of 50 PROs reported identifying a pattern of quality concerns based on complaints during the whole fifth contract period.

Occasional voluntary corrective actions. Sometimes facilities took initiatives to implement corrective actions before the PROs even confirmed that a quality-of-care concern existed. In those cases, the facilities took action based on the PROs' letter indicating that a *potential* quality-of-care concern existed. In those cases, the facilities were generally familiar with the PRO review process. In our review, we found six examples of such voluntary corrective actions. Four involved hospitals; one, an ambulatory surgical center, and; one, a skilled nursing facility. In each case, the voluntary actions involved improved or changed policies or in-service training.

Mediation represents a questionable alternative intervention. Five PROs piloted mediation as an alternative for resolving beneficiary complaints.³² In theory, mediation holds promise. It attempts to resolve disputes for beneficiaries by bringing together the beneficiary and provider or practitioner with a skilled mediator to foster agreement. However, the pilot—which was very limited in scope—raises significant questions about its applicability to beneficiary complaints. It was labor-intensive, involving considerable outreach and education to all parties. In the end, 28 of 58 beneficiaries accepted the PROs' offer of mediation, and of these, only 11 providers agreed to mediate as well. Bringing together a beneficiary and provider or practitioner can present a burden to both parties, particularly a frail beneficiary. Furthermore, there is likely to be a perceived imbalance of power between the participants. The pilot's experience in reaching resolutions between the parties was poor: just 3 of the 11 mediation cases ended up resolving their concerns to the beneficiaries' satisfaction.

The evaluation of the mediation pilot recommended that mediation be tested on a larger scale before implementation.³³ Among the unanswered questions left by the pilot are: What types of complaints are appropriate/inappropriate for mediation? Should the severity of harm be considered? What role would medical record review have in mediation? To what extent is mediation a burden to complainants who may be elderly or frail? How does mediation serve as a beneficiary protection if there is no intervention or follow-up? Do the

benefits of mediation justify the resources spent on training PRO staff and educating providers and beneficiaries?

Quality Improvement Orientation

An effective complaint process guides quality improvement.

Quality improvement projects rarely stem from complaints. Complaints have been a poor source of information on which to base quality improvement projects, which are the focus of the PROs' contracts with CMS.³⁴ The difficulties in identifying a pattern of complaints coupled with the PROs' current contracts, which stress national quality improvement projects as opposed to local projects, make complaints an unlikely source for such projects. Even under their last contract, under which local projects played a larger role, just 1 of 50 PROs reported implementing a quality improvement project based on beneficiary complaints.³⁵

Responsiveness

An effective complaint process provides regular, clear, and substantive responses to complainants.

Limited responses. We found that beneficiaries generally received correspondence from the PRO twice: once at the beginning of the complaint process when the PRO acknowledges the complaint and explains the process, and again at the close of the review when the PRO sends a final letter(s). In our review of 82 complaints at 3 PROs, we found minimal documentation of ongoing written communication between PROs and beneficiaries during the review process, even though the PRO manual instructs PROs to "recontact the complainant whenever you experience any delays with your review and provide the reason for the delay."³⁶ We did, in fact, find delays in the review process to be common. In some cases, however, we did see evidence of beneficiaries calling and discussing their complaints with the PROs during the review process.

Consent for disclosure remains problematic. Current procedures require PROs to obtain consent from the physicians who provide the care in question before the PROs can share their review results with beneficiaries (however, on July 9, 2001, a Federal district court judge found that these procedures are contrary to Federal law).³⁷ Without that consent, PROs can respond to beneficiaries' complaints only in the most general way. But PROs have a difficult time obtaining physician consent, particularly when the medical record review identifies quality-of-care issues. PROs obtain consent in just 21 percent of complaints where a quality-of-care concern is confirmed. They obtain consent twice as often—42 percent—when no concern is confirmed.³⁸ Because complaints often involve

multiple care settings and physicians, obtaining consent can be complex if only some physicians consent. As a result of this consent requirement for complaints with several concerns, we also found that beneficiaries commonly receive multiple final response letters from the PRO, each letter dealing with a single aspect of the complaint. In one case, a beneficiary received eight final response letters from the PRO, all on the same day.

Vague language. Our previous study defined a substantive response as including three components: (1) what the PRO did to investigate the complaint, (2) what the review revealed, including whether a quality-of-care problem was confirmed and, if so, the nature of the problem, and (3) if a quality-of-care problem was confirmed, what action the PRO took based on it.³⁹ Overall, not all PROs are meeting all three components. We reviewed over 100 final letters to beneficiaries from the PROs responding to our survey and found PROs vary widely in the type and quality of information they provide beneficiaries. We often found the letters to lack plain language and even include intimidating references to statutes and regulations (see box).

**Actual Language from Final
PRO Response to a Complainant**

*“THE FOLLOWING STATEMENT IS REQUIRED
TO PROTECT CONFIDENTIALITY. . .
UNAUTHORIZED DISCLOSURE OF PRO
CONFIDENTIAL INFORMATION MAY RESULT
IN A \$1000 FINE AND/OR 6 MONTHS
IMPRISONMENT IN A FEDERAL
PENITENTIARY.”*

All letters did explain that PROs investigate complaints through medical record review—information also spelled out in PROs’ initial letters acknowledging the receipt of the complaint. However, 24 percent of the final letters excluded a summary of the original complaint. We also found the responses to fall short of describing what the review revealed. Even when PROs received consent, some used language so vague that we had difficulty determining the nature of the problem.⁴⁰ Likewise, the PROs used vague language in describing their follow-up of confirmed problems, offering explanations such as “appropriate action has been or is in the process of being taken to prevent problems of this type from occurring in the future.”⁴¹

CMS does provide PROs with a manual to guide and standardize how they operate, including sample letters to complainants. Despite specific instructions for PROs not to use the samples as form letters, many PROs do just that, without providing any case specific details. Through our survey and site visits, many PRO officials reported finding the manual to be both confusing and of limited usefulness.⁴²

Beneficiaries frustrated. PROs reported, both through our survey and site visits, that beneficiaries are often unsatisfied after the PRO completes its review and want closure after months of waiting. They want to know what specific actions the PRO took in response to their particular complaints.

Timeliness

Each step in an effective complaint process is completed within an established, reasonable time frame, and mechanisms exist to deal with emergent complaints in an expedited manner.

Established time frames difficult to achieve. PROs continue to face difficulties in meeting CMS' prescribed time frames for completing their reviews of beneficiary complaints. Since our 1995 inquiry, CMS shortened the target time frames considerably, from 220 to 150 days.⁴³ Despite the reduced time frames from CMS, 43 of 55 complaints we reviewed that had complete date information exceeded the allowed time frames for review.⁴⁴

PRO officials identified a few major obstacles that prevent a more timely process. Collecting medical records from multiple care settings can cause delays, particularly when one of the settings is unaccustomed to working with the PRO. Unlike hospitals, settings such as physician offices and home health agencies have had less interaction with PROs, which means PROs may need to educate them to get records. Some PRO officials noted that their lack of authority to deny payments in certain settings can affect how responsive those places are in sending medical records.

In recent pilots, a few PROs experimented with revised approaches to the complaint process, such as using a case manager to manage communications with the provider or beneficiary. The pilot evaluation found this approach to be more timely.

Public Accountability

An effective complaint process makes complaint information available to the public.

Little information available. Neither CMS nor the PROs make much complaint information available to Medicare beneficiaries and other interested parties, such as advocates. CMS does not release any aggregate national data on complaints. In fact, CMS' own data system does not directly count actual complaints, though that number can be deduced through programming.⁴⁵ The data system does count how many medical records were reviewed by PROs due to a complaint. Because one complaint can trigger multiple reviews, that number is a poor proxy for how many complaints PROs actually receive over a given period.

Thirty-six out of 51 PROs reported that they release some complaint information, usually through their annual reports. The most commonly released piece of information was simply the number of complaints received. Fourteen of these PROs reported that they

released information on the types of complaints they received and 15 on the outcome of review.

PROs face two major obstacles to achieving a more effective beneficiary complaint process.

CMS' contracts with PROs treat complaints as a distinctly minor activity. The contracts stress quality improvement and payment error reduction.

CMS' current contract with the PROs divides their functions into six specific tasks. Half of those tasks relate to CMS' Health Care Quality Improvement Program, which has been a major focus of the PROs over the past 7 years. Those tasks include quality improvement projects that are national, local, and related to Medicare+Choice plans. The fourth task concerns CMS' new Payment Error Prevention Program, which is designed to protect the integrity of the Medicare Trust Funds. Together, these tasks represent 79 percent of CMS' estimated budget for all tasks in the sixth contract period (see box). The contract also calls for each PRO to have two leadership positions: a director for the Health Care Quality Improvement Program (tasks 1 through 3) and a director for the Payment Error Prevention Program (task 4).

Estimated PRO Budget for the 6th Contract Period, by Contract Task

<u>Task</u>	<u>Budget</u> (In millions)	<u>Percent</u>
1. National QI Projects	\$237	36%
2. Local QI Projects	\$ 81	12%
3. Medicare +Choice QI Projects	\$ 49	8%
4. Payment Error Prevention Program	\$148	23%
5. Other Contract Activities*	\$122	18%
6. Special Projects	\$ 21	3%

** Mandatory case review is estimated to cost about \$49 million, which is 7 percent of the total estimated budget. Source: OIG Analysis of budget data provided by CMS for the 6th scope of work (excludes information services).*

Despite beneficiary protection being identified elsewhere in the contract as one of three major functions of the PROs, the complaint process falls under task 5 of the contract, labeled "Other Contract Activities."⁴⁶ Representing 18 percent of the estimated budget, the "Other Contract Activities" section serves as a catch-all. It covers outreach and all mandatory review categories, which include complaints as well as hospital-issued notices of noncoverage, among others. Mandatory reviews, however, represent just 7 percent of the total estimated budget (see box). Unlike the requirements for the Quality Improvement and Payment Error Prevention Programs, the contract requires no director assigned to beneficiary protection or mandatory case review.

CMS' oversight of the PROs reflects the focus of the contract, with the most attention on the Health Care Quality Improvement (task 1) and Payment Error Prevention (task 4) Programs. The contract includes some performance expectations for those tasks. CMS did not publish its evaluation standards for the PROs until April 26, 2001, fully 21 months into

a contract period expected to last 36 months. Those criteria require little more than for CMS, through its regional project officers, to monitor electronically submitted data on the medical record reviews conducted by each PRO. Before those criteria were published (for the first 21 months of the contracts), CMS' project officers, located in four regional offices, relied on checklists and site visits to monitor the PROs. We spoke with a project officer in each region, and while they vary in their approaches, they reported that their focus was on quality improvement and payment error prevention. For those that did review the beneficiary complaint process, their review was largely administrative and focused on documentation.

PROs tend to be more oriented to the medical community than to the beneficiary community. This helps them in conducting quality improvement projects but can hinder them in developing a more effective beneficiary complaint process.

Investigating complaints thoroughly—seeking additional cases for review based on complaints and intervening with corrective actions in cases that fall short of the provider or practitioner “grossly and flagrantly” violating standards of care—can undermine the PROs' relationships with the medical community.⁴⁷ The focus of the PROs' contracts puts a premium on those relationships. Without cooperation and support from the physicians and providers, the PROs would be hard-pressed to conduct any of their quality improvement projects. And given how significantly such projects figure in the PROs' contracts and CMS' evaluation of the PROs, those relationships become a priority. In fact, PROs are inherently tied to the medical community. CMS requires PROs to have the support of physicians in their States, which PROs must demonstrate at the start of each new contract. Furthermore, while PRO boards must have one consumer representative—defined as a Medicare beneficiary—all the other members may be physicians and other health care professionals.⁴⁸

The PROs' orientation toward the provider community is not new. In fact, PROs traditionally have exhibited a reluctance to take on a more enforcement-oriented role that might undermine their relationships with the medical community. They have rarely, for example, referred physicians or providers for sanction. PROs have referred just six providers or practitioners for sanction in the past 5 years, and none in the past 2 years.⁴⁹ They prefer educational approaches, which are more in line with their quality improvement efforts, over punitive approaches. This reflects CMS' view of the PRO program as operating in a “penalty-free environment.”⁵⁰ The orientation toward the provider community was reinforced in 1993 with the onset of the Health Care Quality Improvement Program and the parallel decline in medical record review requirements. To date, the PROs' preference for educational approaches remains strong, which leaves little room for a credible complaint process.

RECOMMENDATION

This report focuses on the PROs' complaint process. That process is available in each State for Medicare beneficiaries with concerns about the quality of care they receive. PROs bring a great deal of expertise to the process given their extensive experience in both reviewing medical records and working with beneficiaries. However, we found that the complaint process falls short of providing an effective safety valve for beneficiaries—just as we did 5 years ago. It has major shortcomings: it is hard-to-use, it rarely holds individual providers or practitioners accountable, and its responsiveness to beneficiaries is limited, leaving them frustrated and unsatisfied. Fundamentally, the complaint process represents a minor activity in a program more concerned with overall quality improvement. While fostering improvement represents an important goal, providing beneficiaries with a meaningful complaint process also serves an important goal of protecting beneficiaries from harm.

CMS must exert strong leadership to address the shortcomings we identify and provide beneficiaries with an effective complaint process. In our draft report, we presented a series of recommendations on how CMS could achieve an effective complaint process. In this final report, we have revised our recommendations and present CMS with two options on how it can achieve an effective complaint process. The recommendations from the draft report are fully incorporated under the first option.

CMS should provide Medicare beneficiaries with an effective complaint process that meets the eight criteria identified in our template.

This is our core recommendation. Our template, which is on page 6, spells out the characteristics of an effective complaint process in each of the following eight elements: accessibility, investigative capacity, interventions and follow-through, quality improvement orientation, responsiveness, timeliness, objectivity, and public accountability. CMS has already endorsed these elements in Congressional testimony and in comments on a previous OIG report, calling them “essential.”⁵¹

Below we present two options for CMS to consider in achieving an effective complaint process for Medicare beneficiaries. The first focuses on fixing the process within the PRO program; the second focuses on establishing a complaint process outside of the PRO program. Following the two options, we briefly identify some issues that CMS must address in pursuing either option.

Option 1: CMS could fix the complaint process within the existing PRO program. Toward that end, it must

Make the complaint process more prominent in the PRO program. Increasing the prominence of the complaint process is the first step toward achieving an effective beneficiary safety valve. To make a difference, CMS must give the beneficiary complaint process more stature in the contract. It must remove the complaint process from the category of “Other” and give it its own section. Without the fundamental commitment from CMS for those changes, any efforts to improve the complaint process through policy, contractual, or regulatory changes will be marginal at best. Indeed, CMS should look beyond the PRO program itself for ways to enhance the stature and support of the complaint process. CMS could, for example, enhance the 1-800-Medicare telephone service by adding a menu option about how to lodge a complaint with the PROs.

Giving the complaint process more prominence as a beneficiary protection is in line with CMS’ own mission, vision, goals, and objectives, as spelled out in its Strategic Plan.⁵² In fact, CMS’ Strategic Plan includes a specific objective aimed at protecting beneficiaries from substandard care and identifies an effective complaint mechanism as a strategy for achieving that objective. Furthermore, it emphasizes “the themes of accountability/stewardship and a renewed focus on the ‘customer’” and “a renewed Agency commitment to beneficiaries as the ultimate focus of all CMS activities, expenditures, and policies.”⁵³

Specify its expectations through its contracts with the PROs. CMS should expect a basic level of performance from the PROs in each of the eight elements. It should articulate those expectations in its contracts. The contracts—as opposed to the PRO manual—represent CMS’ best mechanism for articulating those expectations. CMS could consult with the PROs and other stakeholders to develop the explicit expectations element by element. For example, under the accessibility element, CMS could expect that PRO hotlines are easier to find (e.g., by including the numbers in CMS publications and requiring better listings in phone books under the yellow pages or blue government pages). It should expect that those numbers are also answered appropriately. Under investigative capacity, it should clarify its expectations for referral relationships and follow-up with entities such as survey and certification agencies. Under responsiveness, it could expect the kind of substantive responses we called for in our report 5 years ago (which would also reflect the July 9, 2001 findings of a Federal district court judge, who ordered the Department to instruct PROs to disclose the results of PRO complaint investigations to beneficiaries).⁵⁴

Consider different contracting approaches for the complaint process. The shortcomings we identify in this report are serious. They undermine the ability of the complaint process to function as an effective safety valve. They may be so serious, in fact, as to warrant an overhaul of how the PRO program is structured, financed, and managed. It may be time to search for some creative solutions. For example, as PRO quality improvement projects tend toward more national—as opposed to local—approaches to benchmarking, so too, perhaps, could complaint determinations. Below are three contracting options CMS could consider.

First of all, CMS could modify the current contract with the PROs. In modifying the contract to give the complaint process more prominence, CMS could require each PRO to have a leadership position devoted to beneficiary protection, parallel to the directors called for in the contract to oversee the Quality Improvement and Payment Error Prevention programs. It should specify measurable performance expectations for the complaint process. Of the three options, this option would likely offer the most flexibility. But, because of the PROs' existing orientation to providers, it could make achieving a more prominent complaint process difficult.

Second, CMS could consider a separate contract with the PROs. Such a separate contract should focus on the whole complaint process, the related outreach activities such as the hotline, or some parts of each. Some PROs would likely develop into complaint specialists through this approach and compete for complaint contracts in multiple States. This approach has the advantage of a contract with a singular mission, but could result in some coordination problems within or among PROs.

Third, CMS could consider a subcontract through the PROs. Like the second option, this approach gives the complaint process more prominence by allowing it to be the singular mission of the subcontract but shares the same potential problem with coordination. This approach would open the field of potential contractors to include any organizations capable of delivering the subcontract's requirements for an effective complaint process. Such organizations would compete to win the subcontract, which PROs would manage.

We recognize that some legislative changes may be necessary to carry out some of these strategies.⁵⁵

Hold the PROs more accountable for providing an effective complaint process. CMS should revise and expand its criteria for evaluating the beneficiary complaint process. The current criteria, published in the Federal Register April 26, 2001, make no specific mention of that process. In the meantime, though, CMS should find ways to hold the PROs accountable for their contractual requirements, including developing relevant performance measures and performance incentives. Once again, our template could serve as a framework for CMS in defining such measures and incentives. CMS could work with the PRO community to develop them.

Furthermore, CMS should make information publicly available on the numbers, nature, and outcomes of complaints investigated by the PROs. It could do this through its website and by requiring PROs to include their State-specific information in their own websites and in their annual reports. CMS could work with the PRO community to determine the scope of such information.

Option 2: CMS could establish a complaint process outside of the PRO program.

This option represents a significant departure from how CMS has handled beneficiary complaints to date. It would require legislative change.

As we have defined it, this option must include a mechanism to deal with complaints about facilities as well as individual practitioners. In other words, it must have the same scope as the existing PRO program's complaint authority. It must also have a mechanism to educate beneficiaries about how to register their complaints. CMS has some choices in how to establish a complaint system outside of the PRO program to achieve that. For example, it could establish an entirely new program or contract mechanism focused on complaints and reaching out to beneficiaries about their rights to complain. It could create new mechanisms to deal separately with complaints and outreach. It could even develop alternative mechanisms for mediating certain types of complaints. Or it could build on existing entities that conduct similar work. We explore the latter in more detail below.

State survey and certification agencies already respond to complaints about care provided in certain facilities. Indeed, they are often the frontline responders to adverse events and complaints. They have agreements with CMS to respond to complaints about certain facilities that participate in the Medicare program. These agencies usually have State licensure authorities for certain provider types in addition to the authority stemming from their agreements with CMS. Currently, CMS' agreements with State survey and certification agencies emphasize nursing homes, home health agencies, and hospitals while excluding certain provider types, such as managed care organizations and physician offices. If CMS were to look to these agencies under this option, it would have to modify its agreements with them to ensure that complaints about all provider types would be equally covered.

Medical licensure boards also already respond to complaints from the general public. Unlike State survey agencies, which focus on facilities, licensure boards focus on individual practitioners. In general, the mission of these boards is to protect the public by ensuring that practitioners have the appropriate skills, knowledge, and conduct to practice medicine safely. Responding to complaints about practitioners is a central function of these boards, which have the authority to intervene and take action against an individual's license to practice medicine. CMS already requires that practitioners who participate in Medicare be appropriately licensed by the medical board in their States of practice.

Under this option, PROs would no longer be handling complaints, so the job of educating beneficiaries must also be placed elsewhere. Educating beneficiaries about their rights to complain as well as how to lodge a complaint is critical to ensuring an accessible complaint system. Many groups exist that provide support and outreach to Medicare beneficiaries. The State Health Insurance Partnership Program, for example, already receives funding from CMS to counsel and assist Medicare beneficiaries with health insurance-related concerns. This grant program exists in each State.

Finally, just as we called for under the first option, CMS would have to specify its expectations for each of the elements in our template, hold the complaint system accountable for performance, and make information publicly available on the numbers, nature, and outcomes of complaints. How this would unfold would depend on what a complaint process outside of the PRO program would encompass.

Issues for CMS to Consider

The two options above have advantages and disadvantages for CMS to weigh as it considers how to best achieve our core recommendation, which is an effective complaint process for beneficiaries. Below we highlight those issues we consider paramount.

- To what extent would establishing a complaint process outside of the PROs isolate the PROs from beneficiaries, who are the centerpiece of CMS' programs?
- To what extent would fixing the complaint process within the PRO program exacerbate the tension between the quality improvement and complaint responsibilities of the PROs?
- To what extent does each option require legislative and regulatory changes to ensure that the complaint process functions with the appropriate authority and scope?
- What are the resource implications of each option?

The entities identified in each option—PROs, State survey and certification agencies, and medical licensure boards—all have performance track records in how well they respond to complaints. None of those records is without blemish.⁵⁶ We urge CMS to carefully consider these issues, and others it identifies, as it deliberates on how to best achieve an effective complaint process for beneficiaries.

COMMENTS ON THE DRAFT REPORT

CMS did not provide detailed comments on the recommendations in our draft report. We look forward to receiving such comments in response to this final report. We solicited and did receive comments from the American Health Quality Association, Citizen Advocacy Center, the AARP (formerly the American Association of Retired Persons), and the American College of Physicians-American Society of Internal Medicine. Below, we summarize their comments. We urge CMS to consider the comments we received. Appendix B contains the full text of all the comments.

The American Health Quality Association

The American Health Quality Association agreed that CMS and the PROs should do more to make the complaint process more well-known and responsive to beneficiaries. To do so, the Association called for a reconfiguring of the complaint process and its funding to better integrate the principles of quality improvement within it. The Association called for CMS to implement a mediation and case management within the complaint process.

Citizen Advocacy Center

In its comments, the Citizen Advocacy Center emphasized that PROs are the appropriate entities to handle beneficiary complaints because of their unique expertise, access to records, and authority. It also emphasized beneficiaries' rights to be heard and rights to redress. The Citizen Advocacy Center noted its support for the PROs' focus on quality improvement and its view that a viable complaint process can be integrated into the quality improvement program. It identified further actions for CMS and the PROs to take to improve the complaint process.

AARP

AARP endorsed our template for an effective complaint process and found our recommendations useful. It noted that while it supports the quality improvement focus of the PROs, that focus does not preclude a more effective complaint process. It emphasized the importance of outreach and that PROs need to enhance their reputations as aggressive overseers of quality that value beneficiary input. AARP further recommended that CMS consider contract changes that would allow complaint reviews to be conducted by other regional PROs, thereby protecting the local quality improvement role.

American College of Physicians-American Society of Internal Medicine

Like the other commenters, the American College of Physicians-American Society of Internal Medicine agreed that an effective beneficiary complaint process is key to ensuring quality of care. It expressed its support for the current quality improvement focus of the PROs and emphasized that an improved complaint process can co-exist without

compromising quality improvement. It further recommended that the complaint process be improved through making it more accessible and easier to use, including an informal complaint resolution process, and specifying more precisely what information a PRO can release that balances beneficiaries' need for responsiveness as well as the trust of the medical community.

Profile of Complaints Reviewed

Below we highlight information abstracted from the complaint files we reviewed at three PROs. We looked at 82 complaints in all, 16 of which had no confirmed quality-of-care concerns and 66 of which had at least 1 confirmed quality-of-care concern. Overall, we found complaints to be complex, ranging in types of concerns and care settings.

Sources of Complaints. PROs receive complaints from a variety of sources. Complainants either mail their written complaint directly to the PROs or allow PRO hotline staff to transcribe their complaint over the phone. While most complainants are Medicare beneficiaries or their representatives, some complaints are submitted anonymously. Of the 82 complaints we reviewed, 13 were referrals from other entities. Most of these referred complaints came from CMS and Medicare fiscal intermediaries.

Complaint Types. Complaints can raise a variety of allegations. Of the 82 complaints we reviewed, we identified 297 separate concerns that complainants wanted the PROs to investigate. On average, each complaint raised 3.6 concerns; one complaint had as many as 9 concerns.

We organized these concerns into four main categories:

1. Technical quality concerns, which question clinical expertise and decisions, such as the appropriate use of medications;
2. Service quality concerns, which question facility maintenance and solicitude with patients, such as facility temperature and the friendliness of staff;
3. Administrative concerns, which question general medical office management, such as errors in billing;
4. Other concerns, which question issues beyond those of technical quality, service quality, and administrative concerns, such as instances of abuse and neglect.

The table on the next page summarizes the number and percentage of each of those complaint types in the cases we reviewed. Overall, more complaints involved technical quality concerns than other types.

Type of Concern	Total Number of Concerns	Percent of Total Number of Concerns
Technical Quality	219	74%
Service Quality	43	14%
Administrative	11	4%
Other	23	8%
Unknown	1	< 1%
Total	297	100%

Note: N=82 complaints

Source: OIG analysis of beneficiary complaints from three PROs, 2000.

One complaint can have a mix of these types of concerns, for example:

- C A beneficiary raised a technical quality concern that during his bladder surgery in an ambulatory surgical center he suffered complications that were improperly treated. The surgical center transferred him by wheelchair to a hospital six blocks away. He called this transfer method “a traumatic ordeal” as he was wheeled down the street dressed in a hospital gown with his family following him. This transfer method involved a service concern.
- C The wife of a Medicare beneficiary raised a quality concern that her husband’s rehabilitation center discharged him to a skilled nursing facility still ill with an infection. She then questioned the service of the nursing staff who did not give her regular updates about her husband’s health, especially about his decrease in appetite.
- C A Medicare+Choice beneficiary complained that he had used all of his lifetime inpatient mental health benefits because physicians in a hospital’s alcohol and drug detoxification unit, psychiatric unit, and emergency room improperly admitted and treated him. This complaint raised not only administrative concerns that he was incorrectly billed for the care he received, but also technical quality concerns that he received unnecessary and harmful care.

Care Setting. Complaints can also raise concerns about care given in multiple health care settings, such as hospitals, skilled nursing homes, emergency rooms, and physician offices, among others. From the 82 complaints we reviewed, 25 complaints concerned care given in 2 or more care settings. Five of these 25 complaints involved 3 care settings.

The table below summarizes the number of complaints that involved each care setting. Some complaints involved more than one care setting. Most complaints involved hospitals, but skilled nursing facilities and emergency rooms made up a significant number as well.

Care Setting	Number
Acute Care Hospital	44
Skilled Nursing Facility	22
Emergency Room	20
Physician Office	16
Home Health Agency	2
Rehabilitation Center	2
Ambulatory Surgical Center	1
Psychiatric Unit in Acute Care Hospital	1
Free-Standing Psychiatric Hospital	1
Physical Therapy	1
Radiological Center	1
Hospice	1
Outpatient Care Facility	1

Note: N=82 complaints

Source: OIG analysis of beneficiary complaints from three PROs, 2000.

Detailed Comments on the Draft Report

In this appendix we present the full text of the comments we received in response to our draft report. They include:

- C Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration)
- C American Health Quality Association
- C Citizen Advocacy Center
- C AARP (formerly the American Association of Retired Persons)
- C American College of Physicians-American Society of Internal Medicine




DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: JUL 13

TO: Michael F. Mangano
Acting Inspector General
Office of Inspector GeneralFROM: Michael McMullan 
Acting Deputy Administrator
Centers for Medicare and Medicaid ServicesSUBJECT: Office of Inspector General (OIG) Draft Report: *The Medicare
Beneficiary Complaint Process: A Rusty Safety Valve*
(OEI-01-00-00060)

Thank you for giving us the opportunity to review and comment on the above-referenced draft report.

We appreciate the work that has gone into the draft. We view responding to beneficiary complaints as an important responsibility, and value your assistance in our efforts to achieve excellence in this program.

We look forward to receiving your final report and recommendations, which we will carefully study for implications as to the future evolution of the program.

Thanks again.



The American Health
Quality Association

March 14, 2001

Mr. Michael Mangano
Acting Inspector General
Department of Health & Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Mangano:

I am writing on behalf of the members of The American Health Quality Association (AHQA), representing the national network of private Medicare Peer Review Organizations (PROs). AHQA appreciates having the opportunity to comment on your draft report titled, "The Medicare Beneficiary Complaint Process: A Rusty Safety Valve" (OEI-01-00-00060).

The OIG has performed a valuable public service in raising the level of debate concerning the Medicare complaint process. In response, AHQA has led the PRO community through active consideration of the criticisms in the draft report, including several meetings with consumer representatives, HCFA officials, and groups of PROs.

AHQA recommends a thorough restructuring of the complaint program. We have concluded that HCFA and its PRO contractors can and should do more to make the beneficiary complaint program better known, as well as more responsive to the consumer. While some of the deficiencies in the report can be addressed directly by the PROs, the resources currently invested in this program by the federal government are insufficient to respond to the many challenges noted in your report. AHQA has sent recommendations to HCFA to accomplish reforms identified in your report and by others with whom we discussed your findings.

Role of the PROs In Improving Health Quality.

The draft OIG report makes some suggestions to remake the PRO beneficiary complaint function into a traditional enforcement program that investigates complaints, fixes blame, and publicly names names. The history of the PRO program suggests there is a better way to use taxpayers' dollars to improve quality.

The Medicare beneficiary complaint program was created in the mid-1980s, at a time when the PRO program was built on reviewing thousands of individual patient medical records, looking for quality failures that may require some form of punishment. The notion prevailing at that time was that bad quality results from bad doctors and bad hospitals. Under this approach, when bad actors were found, punishment would be meted out, and the government or its contractors would publicize the names of those found to have failed quality standards. In 1990, the National Academy of Sciences' Institute of Medicine published an extensive study, urging the Medicare program to invest its quality oversight resources more effectively to address the majority of quality shortcomings in our medical care system. By that time, a great deal of evidence had accumulated that quality problems occur in all

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March 14, 2001
Page 2 of 4

settings and in all clinical practice settings, and affect vastly larger numbers of people than those treated by “bad doctors” or “bad hospitals.” In 1993, clinical quality improvement of the health care commonly provided to older and disabled Americans became the goal of the Medicare PRO program. The PRO program was reshaped to constantly and measurably improve the quality of health care services routinely provided to all Medicare beneficiaries, rather than going after the small number of quality problems resulting from the actions of individual substandard caregivers.

HCFA assigned the PROs to serve a new and previously neglected function: clinical quality improvement. Even today, as noted in the draft OIG report, most quality assurance programs are devoted to enforcement of minimum standards. Except for the Medicare PRO and End State Renal Disease (ESRD) Networks (the latter focused on care provided in ESRD facilities), there are still no HHS or State programs with clinical quality improvement as their primary focus. Most Federal and State programs—including scores of Medicare/Medicaid health facility inspection teams, hundreds of state health professional licensure boards, and innumerable state courts adjudicating malpractice suits—continue to enforce minimum standards of care and impose punishment where bad caregivers are found. OIG identifies numerous shortcomings in the programs and functions that use punitive methods to enforce quality standards, and improvement may well be needed there, but this is not a reason to force the PROs into taking on their role.

In fact, many State health professional licensure boards are considering a move to a quality improvement mode of action precisely because they have discovered what HCFA and the PROs discovered in 1993: that case-by-case enforcement of quality standards is a costly and ineffective means of improving the quality of health care provided to consumers.

In our comments, we make the point that the beneficiary complaint program has not been updated nor integrated into the PRO quality improvement program established in 1993. We recommend that HCFA reconfigure the program and its funding so that quality improvement—including follow up by the PRO to help ensure sustained improvement—become routine attributes of an up-to-date, more effective PRO complaint program. This change will ensure that consumers can rely on the PRO complaint program to ensure that problems they experienced will not happen to anyone else.

Peer Review and Public Disclosure.

We agree with the draft report recommendation calling for disclosure of aggregate information on complaints investigated and their resolution. This approach provides information on the types and dispositions of complaints, and ensures public accountability of the PRO program without violating confidentiality protections essential to the peer review process.

The term “peer review” in the name of Medicare Peer Review Organizations has specific meaning in the Federal law establishing these organizations, and in the usage of this term in State laws governing medical peer review, generally. Peer review is an internal process to secure improved quality by having qualified professionals honestly evaluate and assist one another in improving quality. Peer review committees generally, and the PROs in particular, conduct their work in confidence, without disclosure of their findings. Federal law specifically prohibits disclosure of PRO data and findings. This is an ideal arrangement for conducting the “safe, confidential” quality review advocated by the Institute of Medicine and most investigators of “medical errors” and “patient safety.” The peer review approach recruits those who are both most knowledgeable and most able to improve clinical processes—doctors and other health professionals—to help find adverse events and understand their root causes.

March 14, 2001

Page 3 of 4

PROs report that many complainants are not satisfied with this approach, and many prefer to pursue punitive action with public disclosure of the findings of complaint investigations. We believe the PROs should explain to complainants, at the time when a complaint is filed, that the PROs are focused on preventing quality problems from recurring, rather than figuring out who is responsible for what failings and then punishing people for these failings. PROs should ensure that complainants know their choices, so they may choose instead to rely on a licensing board or the courts for punitive action, should they be seeking punishment or need financial compensation for their injuries.

Sometimes, the peer review process at PROs and elsewhere discovers an individual who should no longer provide a particular service, or who should no longer practice as a health professional. When these individuals are found, the PROs take action to protect the public, up to and including recommending that such individuals be excluded from the Medicare program. The need for such action is rare. In most cases, the calling of such persons to appear at a formal hearing to *consider* exclusion from Medicare is sufficient to motivate improvement in those who had previously resisted the PRO's recommendations.

Make Complaints a Higher Priority. Complaint investigations should be given a higher priority, with designation as a separate task under the PRO contract to better correspond to the importance of the work. PROs report current funding supports about 2 hours per complaint, but experience indicates about 14 hours are needed (and much more if several care settings are involved in the case, as is common in Medicare+Choice complaints).

Increase Outreach. Most consumers are unaware of the PRO complaint process. We concur with the recommendation in the draft OIG report that HCFA request increased resources for outreach in the 7th contract cycle. We believe the PROs and also HCFA itself should conduct education of beneficiaries about this program. Several PROs have reported that both outreach and publicity increase the number of hotline inquiries and complaints submitted for investigation. HCFA should estimate the effect of increased outreach on the volume of complaints. Our discussions with PROs suggest that outreach efforts typically create an immediate local 10-25% increase in hotline and complaint inquiries in communities visited by outreach workers. A wider and more sustained outreach effort will produce a persistent increase in intake and case review volume.

Ensure Full Disclosure of PRO Role. Complainants should be informed promptly that the emphasis of the PRO work on their complaint will be quality improvement, rather than assignment and apportionment of blame among the health care providers and practitioners involved in a case. The possibility of sanction in egregious cases should be explained, as well as other aspects of the process to be undertaken by the PRO. If this approach is not what the complainant is seeking, the PRO staff should provide basic information regarding the complainant's other options (e.g., licensure board).

Utilize a Case Management Approach. PROs should be funded to place trained case management workers on complaint investigations that are formally opened. PROs indicate this, along with full early disclosure of the process they use, improves beneficiary satisfaction with the process. The key to this approach is to assign cases to individual PRO employees (generally RNs), who then stay in contact with the complainant and manage follow up action on the complaint. PROs using this method report a manageable workload is about 20-25 cases per RN at any given time, and estimate an increase in costs of 50-100% over a traditional complaint process. In addition, some PROs have had great success using social workers to interview complainants (who frequently include angry family members). AHQA is willing to coordinate with HCFA to provide a forum during our annual Technical Conference for appropriate training and process improvement by PRO caseworkers.

March 14, 2001
Page 4 of 4

Expand Fact Finding. The draft OIG report cites the rarity of PROs pulling additional medical records when they are investigating complaints, to see if quality problems involving a provider or practitioner are more widespread than the original case, and to look for root causes of a problem. OIG notes that the legal authority to obtain and review these charts is already in place. AHQA agrees with this recommendation, but it is important to provide the resources to examine additional records. At present, PROs have the authority, but not the budget, needed to pull additional charts, analyze them, and include them in the extensive security systems PROs have in place. One of the early lessons learned by congressional investigators in the 1980s is that funding does not automatically follow new work assigned to the PROs by HCFA or by Congress.

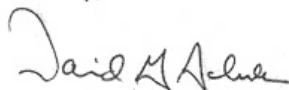
Create a Mediation Option. AHQA disagrees with the draft report's assertion that mediation is not ready for implementation. Mediation is a powerful tool to address complaints when the consumers have not been fully informed, or have misunderstood important information. Consumers typically leave mediation knowing that their concerns were heard. In PRO pilot projects, consumer complainants demonstrated a strong interest in mediation, but practitioners were unfamiliar with the new process and reluctant to join mediation. However, in the pilot projects, little time and energy could be devoted to outreach to the providers and practitioners to explain the mediation option. AHQA recommends HCFA establish a mediation option under the complaint program, with significant and ongoing outreach to provider and practitioner organizations to increase its use.

Follow up Findings with Quality Improvement. Follow up of validated complaints is essential. The current program is constrained by resources and by a limited range of options for follow-up action. AHQA recommends the beneficiary complaint process include quality improvement interventions when the PRO identifies opportunities for improvement. At present, when a complaint is validated, PROs send an "educational letter" to practitioners, indicating areas in which improvement is needed. PROs also have the option of directing a specific corrective action, and, in egregious cases, they may pursue sanctions to exclude an individual from Medicare. However, educational letters are seldom followed up, and most validated complaints do not involve quality problems warranting directed correction or sanction. Working in a more focused and sustained way with providers and practitioners enhances follow up, helps ensure changes in practice are sustained, and gives PROs a means of meaningfully addressing a larger proportion of complaints. HCFA should also fund local quality improvement projects to address problems PROs find in the course of complaint work.

Analyze Complaint Data. Complaints should be categorized and analyzed for patterns, at the state and national level. Solutions found for common problems should be shared with other PROs, in a manner similar to bulletins sent to providers by the Institute for Safe Medication Practices. HCFA needs new resources to create a national database, built from the ground up with the participation of experienced individuals working on beneficiary complaints at the PROs.

Thank you for your willingness to receive suggestions from the PRO community.

Cordially,



David G. Schulke
Executive Vice President



Citizen Advocacy Center

*A Training, Research, and Support Network for Public
Members of Health Care Regulatory and Governing Boards*

April 2, 2001

Mr. Michael Mangano
Acting Inspector General
Department of Health and Human Services
Office of the Inspector General
DHHS/OIG
Room 5246
Cohen Building
330 Independence Avenue, S.W.
Washington DC 20201

Dear Acting Inspector General Mangano:

Thank you for the opportunity to comment on the draft report "The Medicare Beneficiary Complaint Process—A Rusty Safety Valve." (OEI-01-00-00060)

The report points out serious flaws in the Medicare Beneficiary Complaint program and reminds us that the same flaws were identified in a previous OIG report issued in 1995 but no steps have been taken to correct those flaws in the six years since the first OIG report. The report goes on to make four (4) recommendations to HCFA to address the problems with the complaint program. In this letter, we comment on the findings and the recommendations, and add some recommendations of our own for your consideration.

CAC is a training, research, and support network for public members of health care regulatory and governing boards and was created to equip public members to lead their boards toward serving public policy goals more effectively and efficiently. One of the public member networks under the CAC umbrella is known as "PRONET." "PRONET" is the network of beneficiary and consumer representatives who serve on the boards of directors of Medicare PROs. This was the first of the public member networks organized within CAC (in 1987). CAC has managed the PRONET program since its inception, first under contract to AARP, and since 1994 as a not-for-profit 501(c)(3) organization.

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One cannot dispute the finding of both the 1995 report and the current draft report that the Medicare complaint program is very seriously flawed. In 1995, and again this year, CAC considered taking the position that the complaint program is so deeply flawed as to be beyond repair and recommending changing the Social Security Act (which now requires the Medicare Peer Review program to deal with consumer complaints) to remove this responsibility from the PROs.

Why did we consider so drastic a recommendation? Because we feel that, as operated, the PRO complaint programs are of little value to Medicare beneficiaries and their caretakers who utilize the programs to register complaints. We consider it is very nearly a deceptive practice on the part of the PROs to encourage aggrieved beneficiaries to file their complaints (in particular complaints alleging substandard quality of care) when the PROs know how little they are willing and able to do under currently existing rules and operations to (1) fully investigate the complaint; (2) take appropriate remedial action; and (3) inform the complainant specifically about what the PRO discovered in its investigation and what it did to remedy the situation when an investigation confirms that there is a quality of care problem. If the PROs were taken out of the business of handling complaints, they would have to tell any beneficiary who tried to register a complaint with them, "Sorry, you'll have to take your complaint elsewhere. The PRO is a quality improvement organization , and does not handle individual complaints." At least that would be an honest and forthright response.

Why did CAC decide not to recommend that PROs be taken out of the complaint handling business?

Quite simply, we rejected the "get the PRO out of the complaint handling business" option because it would not be in the best interest of Medicare beneficiaries. Congress was correct in giving consumers a right to bring their Medicare quality of care complaints to the agency responsible for overseeing the Medicare program. Starting with President John F. Kennedy, consumer rights to fair treatment in all their marketplace transactions (including health care) have been recognized by every President, Republican and Democratic. Their rights include the right to be heard (in this instance that translates to the right to air grievances) and the right to redress (in this instance that translates into the right to have the government address grievances in a meaningful way when investigation shows them to be meritorious).

Why, then, not give the complaint handling responsibility to another entity? Because PROs have the machinery in place, the expertise, and the access to records to investigate complaints, particularly quality of care complaints. Indeed, investigative capacity and objectivity are the only features of the present PRO complaint process to which the OIG investigation gave satisfactory marks (although the OIG found that the PROs don't do as much

as they should with the information generated by investigations). This puts PROs in a position to make an important contribution to complaint handling and quality improvement, if the flaws in the system were corrected.

Therefore, CAC concluded that it is more appropriate to fix the flawed complaint program, than to abandon it. In the remainder of this response we set forth our own ideas of how this might best be accomplished.

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So that there is no misunderstanding, CAC supports the metamorphosis of the PRO program over the past five years, from one designed to review hundreds of thousands of beneficiary medical records in order to ferret out the so-called “bad apples” (retrospective chart review) to one whose mission is to improve the quality of care provided to all Medicare beneficiaries by all providers. PROs are much more comfortable with the quality improvement mission than they were with the “policeman” role, and the value and importance of their new role is something CAC applauds. CAC is not in anyway trying to turn back the clock. In our view, a viable complaint handling process can be constructed so as to be part and parcel of the PROs quality improvement program. As the draft OIG report made clear, this is not the case today, and that is part of the reason the program is so flawed. Two of the most significant findings in the OIG report tell us, first, that “quality improvement projects rarely stem from complaints” (p 10), and second, “HCFA’s contracts with PROs treat complaints as a distinctly minor activity. The contracts stress quality improvement and payment error reductions” (p 13). Both of these findings stem from the failure of both HCFA and the PROs to consider complaint handling an integral part of the PROs quality improvement program.

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The draft OIG report finds that, “the PROs’ complaint process is an ineffective safety valve for Medicare beneficiaries. It has improved little over the past 5 years” (p 5). To reach this conclusion, the OIG evaluated the current complaint handling program against a well thought out template of eight elements. Based on our experience evaluating governmental programs that receive, investigate, and when necessary take corrective action based on citizen complaints against doctors, nurses, pharmacists, dentists, and other health care professionals, CAC believes the eight elements in the OIG’s template are indeed the elements by which any complaint handling system should be evaluated. The eight elements also provide an appropriate framework around which to build a better complaint handling system.

We believe the draft report correctly evaluates the current PRO complaint handling programs for each of the eight critical elements. (See p 5, table, column entitled “characteristics of the PRO Complaint Process.”) Except for element 7, “objectivity,” the current program is given very low marks. What follows are CAC’s recommendations for how PRO complaint handling programs should be reconstituted in each of the seven areas where it is now flawed.

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Element	Characteristics of an Effective Complaint Process	Characteristics of the PRO Complaint Process
1. Accessibility	Complainants are aware of the system and find it easy to use.	Hotline calls are inconsistently answered. Success of PRO outreach is unknown

CAC Suggested Corrective Action

1. PROs should be required to develop, implement and measure the impact of affirmative outreach programs explaining in simple terms how and when to use the complaint program and what to expect from it. The outreach program should also identify other institutions where aggrieved beneficiaries can file their complaints (state boards of medicine and nursing, and /or health departments or other facility regulators).
2. It is essential that HCFA develop measurement tools to assess the impact of PRO outreach programs, including the effectiveness of the telephone "hot lines." CAC would be pleased to work with HCFA and individual PROs on the development of appropriate measurement tools. It is indeed true that in the PRO program, what does not get measured does not happen. That is why we place so much emphasis on the need for measurement here.
3. Unless there is a change in the current policy under which PROs must obtain physician consent to share with complainants the results of a PRO investigation that confirms a quality of care shortcoming [NOTE: See extensive comments on this topic under "Element 5-Responsiveness," below], PROs should inform consumers on very first contact that the PRO may not be able to share with them in any degree of specificity the results of a PRO investigation, because the physician who is the subject of the complaint must consent to having the results disclosed. This requirement would apply to PRO intake workers (those who talk to consumers on the hotline) and to written correspondence sent by PROs to complainants. With this information, the complainant could decide whether to go forward with the complaint to the PRO, fully aware of the current limitations of the complaint handling program.

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Elements	Characteristic of an Effective Complaint Process	Characteristics of the PRO Complaint Process
2. Investigative Capacity	Appropriate experts, resources and methods are available to assess complaints and determine if they are part of an underlying pattern	PROs rely on medical record review, which is their strength, but they are unlikely to identify patterns. Medical record review is limited to addressing technical quality issues.
3. Interventions and follow-through	Substantiated complaints result in appropriate corrective action. Monitoring assures compliance.	Most common interventions are letters. Corrective actions are rare. Few referrals to other entities. Little follow-up.
4. Quality improvement orientation	Complaints guide quality improvement efforts.	Quality improvement projects rarely stem from complaints: only one PRO implemented a project based on complaints.

Discussion

We will discuss all the above-listen elements collectively in this section.

PROs consider their main mission to be promoting quality improvement. They even refer to themselves (as does HCFA) as Quality Improvement Organizations (QIOs). In their October 2000 report entitled *A Measure of Quality*, the President of the American Health Quality Association (AHQA), William E. Golden, M.D. writes (at p. 2):

“Known as quality improvement organizations...these organizations now work in partnership with all components of the health care system... to ensure the delivery of high-quality, cost-effective medical care to Medicare beneficiaries and other Americans.”

However, complaint handling is not viewed by the PROs as part of their quality improvement efforts. Therein lies the problem. So long as the complaint handling program is considered a step-child, one that diverts the time, resources, and attention of the PROs at the expense of their quality improvement efforts, the program will continue to fail.

The draft OIG report documents the “step-child” status of the complaint program. The program is underfunded; the program is not in any way connected to other quality improvement efforts of the PRO; the program seems to be viewed as a throwback to the days when PROs did not consider themselves QIOs, but were designed to ferret out bad performers.

The draft OIG report documents this unfortunate state of affairs. PRO investigations of quality of care complaints (element #2) “rely on medical record review, which is their strength, but they are unlikely to identify patterns,” the OIG finds. The OIG also finds that “medical record review is limited to addressing technical quality results,” (element #2), and that “Quality Improvement projects rarely stem from complaints” (Element #4 quality improvement orientation). The OIG goes on to find that even when a quality of care failure is confirmed, “Most common interventions are letters. Corrective actions are rare.” (Element # 3)

Contrast this with the approach of the Joint Commission on Accreditation of Health Care Organizations (JCAHO) “Sentinel Events” program. This program deals with (investigates) individual cases and it also issues sentinel event alerts which provide all institutions with an analysis of the events (root cause analysis) leading to the incident, and advise readers of steps each can take to avoid a similar incident in their own settings. JCAHO periodically analyses all the sentinel events reported to it, seeks out patterns and develops, publicizes and promotes corrective and preventative actions. It is a good example of how analyses of individual cases can lead to pattern analysis, which in turn can lead to systemic quality improvements.

It is what the PROs could do if they began to think of quality of care complaint handling as part of overall quality improvement.

CAC Suggested Corrective Action

CAC recommends that the PRO complaint program be reconfigured as follows:

1. When investigating a quality of care complaint, review more than the medical records related specifically to the complaint. Treat every quality of care complaint not only as an individual incident, but also as a potential identifier of a systemic pattern of behavior.
2. When investigating a quality of care complaint, take a root cause analysis approach. Cast the investigation to examine system flaws, product and equipment failures, as well as evidence of substandard clinical skills or knowledge deficiencies. Be especially sensitive to the possibility that a thorough investigation may well expose failings in the actions of the complained-against physician(s) or other practitioner(s) as well as in systemic or equipment failings.
3. When a thorough investigation is completed, and a quality of care problem is confirmed, analyze the likely causes of the quality of care deficiency, and develop a corrective action plan(s) for the practitioner(s) or health care system or both.

4. Require the hospital or other organization and/or the practitioner(s) to implement the corrective action plan, and to make periodic reports to the PRO on its implementation and successful completion. Monitor compliance with corrective action plans by individuals and organizations.
5. Periodically assess patterns of substandard practice and other identified failings and publish these findings. Identify and evaluate corrective action plans, and publish reports on their impact in improving quality of care. Develop training programs to address identified failings.
6. Require PROs to turn over to the appropriate state licensing boards the names of individual practitioners in those cases where the investigation finds that the substandard practice confirmed by the investigation is so serious that it warrants review by the licensing board. The threshold for reporting to the state licensing board should be potential serious harm to public health or safety. We know from the record, and from our own unsuccessful efforts a decade ago to change the situation, that PROs like neither to sanction physicians nor to refer them to medical boards. Without doing violence to the ideas expressed here that complaint-handling should be part of the PROs' quality improvement program, there is a moral, ethical, and legal responsibility to assure that physicians who pose a threat to public health and safety be removed from practice unless and until their performance is brought up to at least minimum standards. As much as the PROs do not relish the policeman role, they have to take steps to turn seriously substandard practitioners over to a policing authority. That authority is the state licensing board. This responsibility cannot be ducked.

We realize that the program we have set forth may require additional resources. We agree with the draft OIG report that some of the reasons the existing complaint handling program is flawed are that it does not have a line-item budget, it is not measured to determine its impact on improving quality, and it is not built into PRO operations as an important element of quality improvement.

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Element	Characteristics of an Effective Complaint Process	Characteristics of the PRO Complaint Process
5. Responsiveness	Responses to complainants are regular, substantive, and clear.	Confidentiality regulations continue to preclude PROs from responding substantively; physicians often fail to consent to disclosure. PROs vary in their responses; they report that beneficiaries are frustrated.

Discussion

Virtually all of the recent bad press about the PROs complaint handling program has centered around the fact that under current regulations (which are being challenged in Federal court in a citizen law suit), complaining beneficiaries cannot be told the results of a PRO investigation, even when the investigation confirms a quality of care problem, unless the physician who is named in the complaint agrees to have the investigatory findings released. It comes as no surprise that physicians are reluctant to allow negative information to be disclosed.

It is not our intention to argue the legality of the current regulation. As mentioned, the case is now before the courts and will be resolved in due course.

However, so long as the current policy is to give veto power to physicians over release of the results of a PRO investigation, it is clear to us that the program will be severely criticized by all consumer advocates. We have discussed this policy at length with beneficiary members of the PRO boards of directors, and every one of those to whom we have spoken finds this policy to be unjustifiable. To give physicians veto power over release of information by an oversight body, all in the name of due process, is a policy that is hard for consumers, their representatives, or the media to understand.

Until HCFA decides on its own to change this policy, or until the courts require such a change, at the very least, PROs should be required to disclose the policy and its impact to complaining beneficiaries. (See our comments under Element #1, "Accessibility," above.) Complainants should be told "You may wish to file your complaint with the board of medicine, which is not bound by this non-disclosure rule should their investigation lead to a disciplinary intervention," or something to that effect.

But that is only a stop-gap measure. More than a band-aid is needed. Set forth below are CAC's recommendations.

CAC Suggested Corrective Action:

HCFA should issue a new regulation regarding what will be made public. The new policy should incorporate the following concepts.

1. All complaints alleging quality of care issues, where there has been death or serious injury (that is, not minor complaints), should be investigated on a priority basis.
2. The investigation should be comprehensive, as described in our comments earlier in this letter.

3. When the investigation is completed, and a quality of care problem confirmed, each PRO will follow the following protocol regarding public disclosure:
 - (a) If the investigation determines that the quality of care problem was caused entirely by a systems error (or other failure by a hospital or other health care delivery institution), the complainant will be informed in writing (1) the nature of the error, (2) the name of the facility responsible for the error, and (3) the corrective action plan imposed on the hospital or other facility or organization. The names of individual physicians, nurses or other health care professionals need not be disclosed.
 - (b) If the investigation determines that the quality of care problem was caused by substandard performance by a physician or other health care practitioner, the complainant will be told in writing (1) the nature of the quality failure, (2) the name of the physician or other health care professional responsible for the quality failure, and (3) the corrective action plan imposed on the practitioner.
 - (c) If the investigation determines that there was both a system failure and substandard practice by a practitioner, then the complainant will be told in writing (1) the nature of the quality failing, (2) the name of the hospital or other organization or facility responsible for that part of the quality failing that was due to a system failure, (3) the corrective action plan imposed by the PRO on the hospital or other organization, (4) the name of the practitioner responsible for that part of the quality failure determined to be caused by that individual's substandard practice, and (5) the correction action plan imposed by the PRO on the individual physician or other practitioner.

This protocol is meant to apply to complaints where there has been a death or serious injury. We realize that human factors research tells us that there may be little difference in causation between cases in which patients are harmed and cases in which there may have been a deficiency in the services provided, but patients have not been harmed. Sometimes the patient lives, but the practitioner is incompetent. Sometimes the patient dies, but the practitioner is not incompetent. Why then, is CAC differentiating between cases where serious harm or death has occurred, and suggesting that the names of individuals be publicized? The reason is primarily credibility. Just as the Institute of Medicine, in its landmark report "To Err is Human," recommends public disclosure of incidents where death or serious harm has occurred, so too should HCFA recognize that the public will not accept hiding the names of physicians in such cases.

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Element	Characteristics of an Effective Complaint Process	Characteristics of the PRO Complaint Process
6. Timeliness	Each step is completed within an established, reasonable timeframe, and mechanism exist to deal with emergent complaints in an expedited manner.	Most complaints exceed the established timeframes for reviewing complaints.

CAC Suggested Corrective Action

HCFA should require PROs to handle complaints within established time frames. We realize that if the investigations are expanded to be more comprehensive, as we suggest in these comments, then there may need to be an adjustment in the established time frames. CAC stands ready to work with HCFA in developing appropriate time frames.

Element	Characteristics of an Effective Complaint Process	Characteristics of the PRO Complaint Process
8. Public Accountability	Complaint information is made available to the public.	Little complaint information is publicly available.

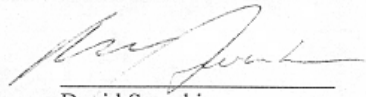
Discussion

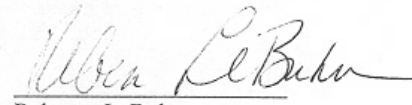
As stated earlier in these comments, PROs could make a valuable contribution to quality improvement if they periodically published reports analyzing patterns discernable from a large number of complaints, and suggesting ways hospitals and practitioners could avoid similar types of problems in the future. The public reporting aspect is one of the more valuable features of the JCAHO Sentinel Events program and public reporting would be equally valuable here. Experience in states where the Department of Health and other entities disclose hospital-specific and practitioner-specific performance

information confirms that providers and practitioners use this information as benchmarks against which to improve their performance so as to get a better "ranking" the next time around.

Thank you for allowing us an opportunity to comment on the draft report.

Sincerely,



David Swankin
President

Rebecca LeBuhn
Executive Vice President



March 26, 2001

June Gibbs Brown
Inspector General
Department of Health and Human Services
DHHS/OIG Room 5246
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Draft Report on the PRO Beneficiary Complaint Process—
“The Medicare Beneficiary Complaint Process: A Rusty Safety Valve”

Dear Inspector General Brown:

The Office of Inspector General has performed an important public service by reassessing the operation of the PRO beneficiary complaint authority. The draft report uses a template of elements, set forth on page 5, for evaluating PRO performance. AARP agrees with this formulation of the elements essential to the operation of an effective complaint process. As in its report five years ago, the OIG concludes that complaint review process needs improvement.

The ultimate goal of the beneficiary complaint process is to improve quality of care in the Medicare program. To accomplish this, the PROs must investigate cases thoroughly and initiate appropriate corrective action where a quality problem has been identified. In many cases a quality improvement intervention may be the best response, but in some cases there should be a referral to state licensing board or to the OIG for sanctions. A plan of correction must be monitored to assure the necessary improvements have occurred. It is not clear that all of this is happening. The draft report concludes that the complaint process rarely holds individual providers or practitioners accountable. Of particular concern among the findings is the lack of pattern analysis in investigating complaints and the absence of follow up after a quality issue is affirmed. The draft report states:

PROs rarely take any action beyond a notification letter to providers and practitioners in response to confirmed quality concerns based on complaints....Occasionally, PRO interventions exceeded the notification letter. In 6 of the 66 complaints with confirmed concerns, the PROs, based on the severity of the review findings, also called for a corrective action plan....(However), we saw no examples of a PRO calling for remedial training, coursework, or special supervision. Furthermore, we saw little evidence of particular follow through by the PRO to ensure that the facilities had in fact changed their policies. We found no example of a PRO pulling extra records for review to determine if the problem persisted, for example.

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Esther “Tess” Canja, President Horace B. Deets, Executive Director



Inspector General Brown
 March 26, 2001
 Page 2

The draft report looks at some root causes of the problem, for example, the heavy emphasis in the PRO contracts on quality improvement projects rather than complaint reviews and PRO concern about alienating the local medical community. The draft report accurately describes the complaint process as a "minor activity in a program more concerned with overall quality improvement" and observes that the PROs are more oriented to the medical community than to the beneficiary community. Much has been said over the years about the inherent conflict of interest between the PROs' duty to conduct quality improvement projects, which absorbs most of their attention and requires good relationships with the local medical community, and their duty to identify and correct quality problems in individual cases, which may generate hostility from practitioners and providers whom they investigate. These problems are not new and the draft report does not minimize them. However, it takes the position, which we strongly support, that the PROs' quality improvement duties do not pose an insuperable barrier to better performance of complaint reviews.

The report recommends steps HCFA can take to encourage the PROs to give more attention to complaint reviews and require more accountability from the PROs, for example set specific performance goals, treat complaint reviews as a separate contract activity, etc. We believe the OIG recommendations are useful.

In addition, we suggest that another contract change be considered that would establish a system whereby the local PRO does not conduct complaint reviews of care provided within its own jurisdiction, but instead such cases would be assigned to another PRO within the region, or perhaps to a regional PRO authority. The goal of such a system would be to shield the local PRO from possible hostile reaction by the local medical community, thereby ensuring that the PRO remains effective in its quality improvement role. (The PRO would, however, be responsible for implementing and monitoring corrective action plans with respect to local providers.)

A review process, no matter how good, will not lead to better quality of care unless beneficiaries use it. As in its report five years ago, the OIG observes that the volume of complaints by beneficiaries is quite low. There are several possible causes.

The draft report notes that the complaint review process leaves beneficiaries "frustrated and unsatisfied." It appears that many PROs do not communicate well with beneficiaries and do not make it easy for them to initiate complaints. Another major problem is that the PROs do not inform beneficiaries of the results of investigations unless the practitioner involved consents to release of that information. While there has been discussion of requiring the PROs to disclose the results in a wider range of situations, thus far little has changed in actual practice.

AARP continues to believe that the secrecy surrounding the results of the investigation discourages some would-be complainants from coming forward. At the same time, however, it appears that beneficiaries' failure to use the complaint review process in significant numbers may

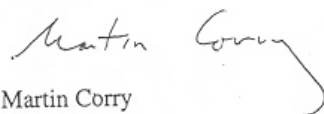
Inspector General Brown
March 26, 2001
Page 3

be caused as much by ignorance as by frustration. After more than ten years, most beneficiaries still do not know that the PRO review process exists or understand how it works. There clearly needs to be more outreach and education, and the message to the public should accurately describe what PRO review will accomplish and not create false expectations. However, public awareness that PROs exist is not enough. The PROs need to become known in the community as aggressive watchdogs which value and facilitate beneficiary input. This means that PROs which are not communicating well with beneficiaries, energetically investigating cases, and imposing and overseeing appropriate remedies have to start doing so. Those which already perform well need to convey to the public that they are effective and user-friendly.

Thank you for this opportunity to review and comment on the draft report. An effective complaint review process could contribute significantly to improving quality of care. Although the quality improvement projects remain the major PRO function—one which AARP strongly endorses—we nevertheless believe the PRO mandate to improve quality requires the PROs to do more. We agree with the OIG that the complaint review function can be strengthened without compromising quality improvement projects. We commend the OIG for taking a positive approach toward fixing the problems.

If you have questions or if we can be of any further assistance, please contact Mary Ellen Bliss of our Federal Affairs staff at 202-434-3781.

Sincerely,



Martin Corry
Director
Federal Affairs

March 7, 2001



American College
of Physicians
American Society
of Internal Medicine

Mr. Mike Mangano, Acting Inspector General
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Dear Mr. Mangano:

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM), representing over 115,000 physicians who practice internal medicine and medical students, is pleased to provide comments on the Office of Inspector General's (OIG) draft inspection report entitled, "The Medicare Beneficiary Complaint Process: A Rusty Safety Valve."

ACP-ASIM agrees with OIG that an effective Medicare beneficiary complaint process can be a vital element in assuring quality of care rendered to this population. It is clear from the draft report, as well as OIG's 1995 report on the same subject, that the beneficiary complaint process appears to be underutilized. We agree that steps should be taken to make the complaint process better known and more accessible to beneficiaries, but without compromising the hard earned trust that has been built between Peer Review Organizations (PROs) and the physician community.

However, we strongly disagree with OIG's contention that PROs intentionally under-prioritize the handling of complaints as a way of winning favor with the medical community. Also, we believe it is crucial that PROs retain their principal emphasis on education and quality improvement, and not endanger that role by placing a higher priority on enforcement activities as suggested by OIG. This would not only do great damage to the relationship between PROs and physicians, it would also undermine the trust needed to support reporting of medical errors, critical to the ground swell of patient safety initiatives that have recently come to the fore.

ACP-ASIM feels strongly that the beneficiary complaint process can be vitalized and given the priority it deserves without compromising the positive, pro-quality, non-punitive educational relationship that exists between physicians and PROs. We believe this can be accomplished without significant changes in the PROs' scope of work and/or budget allocations. Our recommendations are as follows:

1. The beneficiary complaint process should be better publicized and made more easy to access and use. We believe HCFA should work with advocacy groups such as the AARP to publicize the availability of the beneficiary complaint

Letter to Mike Mangano, page 2

process and develop and distribute easy to use instructions and forms for submitting such complaints to PROs. This would include clear timelines for PROs to complete investigations and report findings to beneficiaries. However, this must be done in a manner that does not result in an avalanche of specious or misdirected (non quality of care) complaints, triggered by language that unfairly casts mistrust upon providers (as was the case with the initial "Who Pays, You Pay" campaign, prior to the revisions made by OIG to address concerns expressed by ACP-ASIM and other medical organizations). As OIG is aware from its analysis of its own 1-800-HHS-TIPS Hotline, the vast majority of calls received are **not** substantive complaints about the quality or legitimacy of care received and billed. This leads to our second recommendation, below.

2. PROs should offer beneficiaries an informal complaint resolution process to try to resolve beneficiary concerns and avert the filing of a formal complaint requiring an in-depth investigation. We believe PROs can do themselves and the beneficiary community a great service by hearing and intervening in beneficiary complaints before they are filed formally. This would help change the perception that PROs are only peer-oriented and would raise their credibility in the beneficiary community. HCFA might have to supplement PRO budgets to handle an increased volume of calls resulting from publicizing the beneficiary complaint process as recommended above, but the benefit would be increased awareness of, and earlier intervention in, problems which are surfaced. Like the OIG Hotline, incoming beneficiary calls could be triaged for most efficient handling (with referrals back to physicians themselves or Medicare contractors and carriers for non quality of care issues). For complaints that are filed formally, HCFA might wish to consider installing a PRO mediation process to try to address beneficiary concerns before having to commit PRO resources to a formal investigation process.
3. HCFA should give explicit instructions to PROs on the nature and content of information that can be released to a beneficiary pursuant to a complaint investigation while preserving the requirement that physicians first give their consent for release of personally identifiable information that is developed as a result of the complaint investigation. HCFA must be explicit in instructing PROs on what information they can and cannot release in the absence of physician consent. The intent should be to balance the beneficiary's right to know about the disposition of a complaint and the physician's right to insist that personally identifiable information be kept confidential. It might also be useful for HCFA to serve as a clearinghouse for release of cumulative (not personally identifiable) PRO investigative findings, to ensure that all beneficiaries are treated equally, and that there is uniformity in the information PROs release. We believe one of the major impediments to PROs' release of investigative findings has been the fear of compromising physician

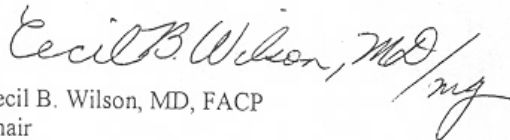
Letter to Mike Mangano, page 3

confidentiality in cases where a physician does not consent to release of personally identifying information. Rather than risk violating this requirement, PROs have taken a conservative approach to releasing (non personally identifiable) investigative findings that can and should be released to the beneficiary under current program requirements. HCFA's clear and precise guidance in what information PROs can release would go a long way to improving the potency and value of the beneficiary complaint process. We believe strongly that the requirement that a physician give his or her explicit consent to the release of personally identifiable information, obtained in the course of an investigation of a beneficiary complaint, must be maintained. Confidentiality is essential if the PRO program is to continue to have the degree of trust in the physician community that is required for it to function as a quality improvement organization rather than being viewed by physicians as an enforcement and sanctioning arm of government.

In summary, ACP-ASIM believes the beneficiary complaint process can be fortified in a number of ways which do not compromise the strong bond of trust which exists between physicians and PROs, essential for the vital educational, quality enhancing impact PROs have on health care in their local communities. These fortifications would include expanding beneficiary awareness of the complaint process and making the process more accessible and easy to use, offering an informal PRO complaint resolution process, and specifying in precise fashion which types of information can be released pursuant to a PRO investigation, and ensuring this information is responsive to beneficiary needs. All of these improvements in how PROs respond to beneficiary complaints will have the added benefit of complimenting the burgeoning array of national patient safety initiatives, as data on systemic sources of error will be easier for PROs to collect when protection of physician confidentiality is not at issue.

As always, ACP-ASIM appreciates the opportunity to work cooperatively with the OIG, and is hopeful our recommendations have been helpful. Please contact Mark Gorden, Senior Associate for Managed Care and Regulatory Affairs, at (202) 261-4544, if you have any questions concerning this correspondence.

Sincerely



Cecil B. Wilson, MD, FACP
Chair
Medical Services Committee

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Endnotes

1. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509.
2. 42 U.S.C. sec 1320c-3 (a) (14).
3. U.S. Department of Health and Human Services, Office of Inspector General, *The Beneficiary Complaint Process of Medicare Peer Review Organizations*, OEI-01-93-00250, November 1995.
4. Health Care Financing Administration, *Peer Review Organization Manual*, 5020: 5-11 through 5-12 and Exhibit 5-17 through Exhibit 5-18.
5. The California PRO, California Medical Review Incorporated (CMRI), in collaboration with the University of California at San Francisco, RAND Corporation, and Center for Social Redesign, *The Medicare Beneficiary Complaint Alternative Methods Study*, 500-96-P535, Modification P00014, October 1999.
6. 66 Fed. Reg. 93, 25389, May 14, 2001.
7. The PROs' fifth contract period began April 1996. The sixth contract period began in August 1999 and is expected to last for 3 years.
8. We excluded the PROs for Puerto Rico, American Samoa, Guam, and the Virgin Islands from this survey.
9. We asked for final response letters where: (1) no quality-of-care concern was identified, (2) a quality-of-care concern was confirmed, and the practitioner consented to disclosure, and (3) a quality-of-care concern was confirmed, and the practitioner declined to disclosure.
10. Health Care Financing Administration, *The Successful PRO in 5 Years*, Baltimore, MD, November 8, 1994.
11. Sixth Scope of Work, R.F.P. No. CMS-99-001/ELH, March 1, 1999, p. 13.
12. *The Beneficiary Complaint Process of the Medicare Peer Review Organizations*, 3.
13. U.S. Department of Health and Human Services, Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050, July 1999.
14. For further discussion see: Mark R. Yessian, "State Medical Boards and Quality Assurance," *Federation Bulletin: The Journal of Medical Licensure and Discipline* 79 (1992) 5: 126-135; "How Can State Medical Boards Compete in the Quality Assurance Marketplace?," *Federation Bulletin: The Journal of Medical Licensure and Discipline* (1994) 2: 102-108; "From Self-Regulation to Public Protection: Medical Licensure Authorities in an Age of Rising Consumerism," *Federation Bulletin: The Journal of Medical Licensure and Discipline* 81 (1994) 3: 190-194.

See also: Timothy S. Jost, “Oversight of the Competence of Healthcare Professionals,” in *Regulation of the Healthcare Professions*, Timothy S. Jost, ed. (Chicago, IL: Health Administration Press, 1997); L. J. Finnocchio et al., *Strengthening Consumer Protection: Priorities for Health Care Workforce Regulation* (San Francisco, CA: Pew Health Professions Commission, 1998); and Carl F. Ameringer, *State Medical Boards and the Politics of Public Protection* (Baltimore, MD: The Johns Hopkins University Press, 1999).

15. James T. O’Reilly, “Elders, Surgeons, Regulators, Jurors: Are Medical Experimentations’ Mistakes Too Easily Buried?” *Loyola University Chicago Law Journal* 31 (Spring 2000) 3: 355.

16. U.S. Department of Health and Human Services, Office of Inspector General, *The External Review of Dialysis Facilities: A Call for Greater Accountability*, OEI-01-99-00050, June 2000.

17. *Medicare End Stage Renal Disease Program before the Senate Special Committee on Aging*, 106 Cong., 1st Sess. (June 26, 2000) (statement of Jeffrey Kang, Director, OCSQ).

18. In 1999, 67 percent of beneficiaries who sought Medicare information from Medicare sources reported that the information they received answered their questions. See Health Care Financing Administration, *FY 2000 Annual Performance Plan*, Baltimore, MD, January 2000: 150.

19. In 1995, we found that 77 percent of Medicare beneficiaries were unaware of the PROs. Our current study revealed no evidence of increased awareness, a conclusion also reached by stakeholders with whom we spoke.

20. Sixth Scope of Work, R.F.P. No. HCFA-99-001/ELH, March 1, 1999: 13.

21. CMS’ method of tracking data from the PROs, the Standard Data Processing System (SDPS) indirectly counts the number of complaints each PRO receives. It counts how many medical records the PROs reviewed in response to complaints. One complaint can involve multiple settings of care, thus multiple records. Based on SDPS data reported by the PROs for the period between August 1997 and July 1999, we arrayed the PROs by the level of outreach activity and numbers of records reviewed due to complaints. Just 3 PROs appeared in the top 10 on both lists.

22. PROs averaged less than 2 outreach activities per 10,000 beneficiaries between August 1997 and July 1999.

23. CMS lists “Increasing the Effectiveness of Dissemination of Medicare Information to Beneficiaries” as a target in its FY 2000 Annual Performance Plan. See Health Care Financing Administration, *FY 2000 Annual Performance Plan*, Baltimore, MD, January 2000: 150.

24. The two PROs that reportedly did not refer service-related complaints handled them slightly differently. In one case, the PRO routinely reviewed the medical record for service complaints. As an example, the official from that PRO noted that a beneficiary might complain about her water pitcher being out of reach, which is a service quality issue. The medical record could, in fact, document that beneficiary’s intake and output and potential dehydration related to an out-

of-reach water pitcher. The official from the other PRO noted that she considered service complaints as potentially the “tip of the iceberg,” and would generally at least “skim the medical record.”

25. CMS’ recent pilot testing of alternative methods for handling beneficiary complaints included a recommendation for structured, in-depth telephone interviews of beneficiaries. See *The Medicare Beneficiary Complaint Alternative Methods Study*.

26. We found a similar pattern when we examined the PROs’ responses to quality-of-care problems they identified through medical record review several years ago. In that study, we found the PROs’ most common response to providers and practitioners responsible for quality of-care problems to be letters, also considered to be educational. (Office of Inspector General, *Educating Physicians Responsible for Poor Medical Care: A Review of the Peer Review Organizations’ Efforts*, OEI-01-89-00020, February 1992.)

27. There are exceptions, of course. At one PRO, the medical director told us about a surgeon whom the PRO had referred for sanction many years ago and who was just returning to the Medicare program. She told us that the PRO will monitor the quality of care given by the surgeon by pulling records for review.

28. The lack of referrals between PROs and State medical boards has been well documented. See Office of Inspector General, *Peer Review Organizations and State Medical Boards: A Vital Link*, OEI-01-91-00530, April 1993 and Citizen Advocacy Center, *Information Exchange Between Peer Review Organizations and Medical Licensing Boards: Report on 50 State Survey*, November 1992.

29. We found PRO referrals to State survey and certification agencies to be more common earlier in the complaint process. For example, PROs will refer complaints to such agencies when they deem the complaint to be about the quality of services rather than the quality of care. In those cases, the PRO would generally not conduct any kind of medical record review at all.

30. This applies unless they identify a gross and flagrant problem.

31. Sixth Scope of Work, R.F.P. No. HCFA-99-001/ELH, March 1, 1999: 32.

32. *The Medicare Beneficiary Complaint Alternative Methods Study*.

33. The small number of mediated beneficiary complaints and the inconsistent criteria for including beneficiaries in the mediation pilot limit the conclusions that can be drawn from the study. The study focused on 58 complaints, of which only 11 involved a provider and complainant who both agreed to mediate. Also, each of the five PROs used different criteria to select complaints for mediation. Inconsistency across PROs regarding whether to limit participation in mediation only to those cases where a medical record review had already been completed raises the question of whether mediation is intended to supplement or replace medical record review. Although a few complainants were satisfied with mediation, unless all complaints also undergo a medical record review, participants in mediation cannot be assured the same

protection as those whose complaints undergo medical record review.

34. CMS estimates that 51 percent of the PROs' budgets in the sixth contract will be devoted to quality improvement activities through either national projects (33 percent), local projects (11 percent), and managed care projects (7 percent). See Sixth Scope of Work, R.F.P. No. HCFA-99-001/ELH, March 1, 1999.

35. This quality improvement project concerned advanced directives.

36. Health Care Financing Administration, *Peer Review Organization Manual*, 5020(A)(1).

37. For current procedures, see *Peer Review Organization Manual* section 5035 and 42 C.F.R. 476. For the recent court decision, see *Public Citizen, Inc. v. Department of Health and Human Services, et al.*, Civil Action No. 00-00731, July 9, 2001.

38. Based on Office of Inspector General review of SDPS data from August 1997 through July 1999.

39. *The Beneficiary Complaint Process of the Medicare Peer Review Organizations*.

40. One PRO routinely provided a chronology of the care provided to the beneficiary during the time in question. While this conveyed that the PRO had indeed reviewed the case carefully, it also could suggest that the chronology represented the results of the medical record review.

41. This is from a sample of final response letters with confirmed problems and consent for disclosure.

42. In fact, after receiving questions from CMS regional office staff in May, CMS completely reversed its interpretation of the need for beneficiary consent to disclosure. Previously, if beneficiaries declined to have their names disclosed in the review process, CMS instructed the PROs to provide no final response whatsoever. Now, CMS allows a final response—which is required by the complaint statute—even where the beneficiary fails to consent to disclosure. (See Health Care Financing Administration, *Disclosure of Complainant's Name in Beneficiary Complaint*, OCSQ TOPS Control Number 2000-13, May 17, 2000.)

43. This applies for complaints with confirmed concerns and no request for re-review. Health Care Financing Administration, *Peer Review Organization Manual*, exhibit 5-19.

44. The 55 complaints included 16 without confirmed concerns, 20 with confirmed concerns but no re-review, and 19 with confirmed concerns and re-review. We used the timeframes appropriate to each category in measuring timeliness. Ten of the 16 complaints without confirmed concerns exceeded the 120 allowed days; 16 of the 20 confirmed concerns without re-review exceeded the 150 allowed days, and; 17 of the 19 confirmed concerns with re-review exceeded the 165 allowed days.

45. According to CMS, the SDPS data system can produce the number of actual complaints if someone programs it to count those records with the same beneficiary identifier and the same

start date as single complaints.

46. Sixth Scope of Work, R.F.P. No. HCFA-99-001/ELH, March 1, 1999: 32.

47. 42 U.S.C., sec. 1320c-5 (b) (1).

48. 42 U.S.C., sec. 1320c-1 (3).

49. Since 1986, PROs have referred 286 physicians and providers to the Office of Inspector General for sanction. PROs made no referrals for FY 1999 or FY 2000. See also Office of Inspector General, *The Sanction Referral Authority of Peer Review Organizations*, OEI-01-92-00250, April 1993.

50. Comments from the CMS Administrator in Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050, July 1999.

51. See *The External Review of Dialysis Facilities: A Call for Greater Accountability and Medicare End Stage Renal Disease Program before the Senate Special Committee on Aging*, 106 Cong., 1st Sess. (June 26, 2000) (statement of Jeffrey Kang, Director, OCSQ).

52. Health Care Financing Administration, *Strategic Plan* (September 1998).

53. *Strategic Plan*, 7.

54. In that 1995 report, we defined a substantive response as including three elements: (1) what the PRO did to investigate the complaint, (2) what the investigation revealed, including whether a quality-of-care concern was confirmed, and if so, the nature of the concern, and (3) if a quality-of-care concern was confirmed, what action the PRO took based on it. See *The Beneficiary Complaint Process of the Medicare Peer Review Organizations*. For details on the Federal district court decision, see *Public Citizen, Inc. v. Department of Health and Human Services*, et al., Civil Action No. 00-00731, July 9, 2001.

55. The Social Security Act calls for the Secretary to contract with a single PRO in each State (42 U.S.C. 1320c-2). Furthermore, it requires PROs to be the entities making final determinations on quality (42 U.S.C. 1320c-3).

56. See the discussion on page 5 as well as *The Beneficiary Complaint Process of Medicare Peer Review Organizations*, November 1995; Office of Inspector General, Department of Health and Human Services, *The External Review of Hospital Quality: A Call for Greater Accountability* and *The External Review of Hospital Quality: Medicare Certification*, both July 1999.